Competing Application Example # 1

Note: This is a copy of a funded grant application. Permission from the Principal Investigator was obtained by NIH staff.

Form Approved Through 05/2004

Department of Health and Human Services

8 1 0 4 4 0 APR 2002

Do not exceed 55-character length restrictions, including spaces.

PI: [redacted]

1 R01 TW[redacted]-01

Dual: AG,ES,EY,MH,NS

IRG: ZRG1 ICP(02)

Council: 10/2002

Received: 04/18/2002

1. TITLE OF PROJECT

Widow inheritance and HIV infection in Kenya

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☒ YES

(If "Yes," state number and title)

Number: [redacted] Title: Global Health Research Initiative Program for New Foreign Investigator

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

New Investigator ☐ No ☒ Yes

3a. NAME *(Last, first, middle)*

3b. DEGREE(S)
MA PhD MPH

3c. POSITION TITLE
Project Coordinator

3d. MAILING ADDRESS *(Street, city, state, zip code)*
[redacted]
Lumumba Health Centre
P.O. Box 1764
Kisumu
Kenya

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Medical Microbiology

3f. MAJOR SUBDIVISION
UNIM Reproductive Health Project, Kisumu

3g. TELEPHONE AND FAX *(Area code, number and extension)*

TEL: [redacted] FAX

E-MAIL ADDRESS: [redacted]

4. HUMAN SUBJECTS RESEARCH
☐ No
☒ Yes

4a. Research Exempt ☒ No ☐ Yes
If "Yes," Exemption No.

4b. Human Subjects Assurance No.

4c. NIH-defined Phase III Clinical Trial ☒ No ☐ Yes

5. VERTEBRATE ANIMALS ☒ No ☐ Yes

5a. If "Yes," IACUC approval Date

5b. Animal welfare assurance no

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)
12/01/02	11/30/07	$50,000	$54,000	$250,000	$270,000

9. APPLICANT ORGANIZATION

Name

Address [redacted]

Nairobi
Kenya

Institutional Profile File Number (if known)

10. TYPE OF ORGANIZATION
Public: → ☒ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER

DUNS NO. *(if available)*

Congressional District

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

Name Jeckoniah Ndinya-Achola
Title Professor and Dean
Address University of Nairobi
Dean's Office, School of Medicine
P.O. Box 19676
Nairobi, Kenya
Tel 254-2-726300 Ext 43769 FAX 254-2-725102
E-Mail hwandaka@ratn.org

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION

Name Jeckoniah Ndinya-Achola
Title Professor and Dean
Address University of Nairobi
Dean's Office, School of Medicine
P.O. Box 19676
Nairobi, Kenya
Tel 254-2-726300 Ext 43769 FAX 254-2-725102
E-Mail hwandaka@ratn.org

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 3a. *(In ink. "Per" signature not acceptable.)* [redacted] DATE April 10, 2002

15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)* [redacted] DATE April 11, 2002

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

We propose to conduct a prospective cohort study to investigate the association between widow inheritance and HIV infection among the Luo ethnic community in Kenya--the community with the highest HIV prevalence in the country. The specific aims of the study are to: 1) assess the association between widow inheritance and acquisition of HIV; 2) examine the relationship between HIV infection and being inherited by a brother-in-law versus by a 'professional' inheritor; 3) evaluate the difference in HIV risk associated with being inherited for companionship and support versus for sexual cleansing; and 4) identify correlates of inheritance overall, as well as of the different types of the practice.

To achieve these aims, we will recruit 992 widows through radio announcements; women's, widow's and church groups; fliers, posters and brochures; health talks in clinics; chiefs' community meetings; and Focus Group Discussions with widows. At visit 1, those who consent will be counseled and tested for HIV. Those seronegative and are willing to join the study will come for visit 2 when they will be interviewed on their sociodemographic characteristics, sexual behavior, and medical history. They will also provide blood specimens for gonorrhoea, HSV-2, syphilis, and trichomonas vaginalis tests. Swabs will be taken from those with genital ulcers to test for haemophillus ducreyi. They will then be followed up quarterly for 24 months, during which time the activities performed at enrolment will be repeated.

Exposure will be inheritance, including the different types of the practice, while the main outcome will be HIV seroconversion rate and the secondary outcomes will be the incidence of the various types of STIs. We shall use Epi-Info software to enter data and to perform crude and adjusted Mantel-Haenszel tests to obtain the relative risk of acquiring HIV and STI given that a widow is inherited relative to those not inherited. Logistic regression analysis will be used to identify which characteristics are independently related to inheritance. The findings will be the first scientific study of this association and will help in designing HIV intervention programs that are informed by research.

PERFORMANCE SITE(S) *(organization, city, state)*

Bondo District Hospital, Bondo Town, Kenya
Siaya District Hospital, Siaya Town, Kenya
Impact Research and Development Consultancy Offices, Kisumu City, Kenya.
UNIM Project Laboratory, Kisumu City, Kenya
Department of Medical Microbiology, University of Nairobi, Nairobi, Kenya.
University of Washington, Seattle, Washington

KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	Organization	Role on Project
[redacted], PhD, MPH	[redacted]	Principal Investigator
Ahenda, Hannington, HND	UNIM Project	Chief Technologist
Bukusi, Elizabeth, MBChB, MPH, PhC	University of Nairobi; KEMRI	Co-Investogator (Ob/Gyn)
Ndinya-Achola, Jeckoniah, MBChB, MSc	University of Nairobi	Co-Investogator (Medical Microbiogist)
Obare, Billy BA (Hons), MA	Impact Research and Dev. Consultancy	Co-Investigator/Coordinator
Vanderstoep, Ann, PhD	University of Washington	Co-Investigator/Mentor; Biostatistician
Weiss, Noel, MD, DrPH	University of Washington	Co-Investigator and Mentor

Name:	Organization	Role on project
To be appointed		2 Clinical Officers
To be appointed		2 Nurse-Counselors
To be appointed		2 Receptionist-Clerks
To be appointed		1 Assistant Lab Technologist
To be appointed		1 Secretary-Accounts Clerk
To be appointed		1 Driver

Investigators

Principal investigator:
The Principal Investigator, [redacted] of the University of Nairobi, has a PhD in Medical Geography from the University of Washington (completed in August 2001). She conducted fieldwork for 15 months in 1999/2000 on the cultural practice of widow inheritance among the Luo ethnic community in Kenya and wrote her dissertation on "Widow inheritance and HIV/AIDS interventions in sub - Saharan Africa: Conceptualizations of 'risk' and "spaces of vulnerability". During fieldwork, she used ethnographic approach to explore why intervention programs have had little success in changing the attitudes and behavior of the community towards the practice of widow inheritance. Primary data was obtained from 66 focus group discussions, 161 open discussions, and 11 key informant interviews while secondary data came from various local and international publications.

In addition, she has an MPH in Epidemiology (International Health Program), also from University of Washington (completed in March 2001 and done concurrently with the PhD). For her MPH thesis entitled "HIV-1 prevalence in circumcised versus uncircumcised Luo men in rural Kenya", she also carried out fieldwork among the Luo ethnic community on another culturally sensitive topic—male circumcision. During her MPH and PhD training, she took methodology courses that have grounded her as a researcher in public health, such as Epidemiology Methods, Biostatistics, Research Methods in Public Health, Quantitative and Qualitative Research Methods in Medical Geography, among others. In addition, she took numerous courses that focused on HIV/AIDS, such as-AIDS: A Multidisciplinary Approach, AIDS, Public Health and the Humanities, Third World Infectious Diseases, Emerging Infections of International Importance, Problems of International Health, and Society and Health. Besides the content and methodology in HIV research obtained from the University of Washington, the PI also has another Masters Degree in Medical Geography from Moi University, Kenya and a Bachelors degree in Education from the University of Nairobi, Kenya. During her Masters Program and also as a faculty at Moi University, she undertook several field studies in Public Health among the Luo community and is very conversant with the cultural practices of the community. Furthermore, the PI herself is a Luo by ethnicity, thus an insider who has been able to get at the depth of the cultural practices of the community and their potential association with public health. At the same time, as one with sound training in Epidemiology and Social Science research, she also brings into the research an outsider experience. The bringing together of both insider and outsider expertise and experience places the PI in a particularly advantaged position to carry out the proposed study.

Appropriateness of work proposed to researchers' experience: The proposed study is actually a response to the main recommendation in the PI's dissertation, that the Government of Kenya is expending a lot of resources to campaign for the eradication of widow inheritance to reduce HIV infection among the Luo ethnic community, yet no study has been done to assess the risk posed by the practice. As a Luo concerned about the high prevalence of HIV in the community (29.8%), the proposed study will provide a scientific basis for designing informed intervention strategies addressing the practice of widow inheritance.

Career development and leadership position of the PI: As a recent graduate who focused her research on culture and HIV/AIDS research among the Luo ethnic community in Kenya, and as a faculty member of a research institution, the award would provide the PI with an opportunity to advance her research career in the area of Public Health in which she has focused most of her training. This award will also enable her to acquire post–training research experience, having completed an MPH and a PhD in 2001. In other words, the award will provide her with an opportunity to put into practice the training acquired at the University of Washington. Furthermore, carrying out in the research will, in turn, benefit the

students the PI is teaching in terms of providing opportunities for fieldwork and keeping them abreast with information on HIV/AIDS based on local research. The utmost interest of the PI is in intervention research. One reason that a lot of interventions in HIV/AIDS in sub-Saharan Africa have not been effectively research–driven is because of lack of research capacity/experience/grounding in this area so that this becomes a useful investment in African human resources in the direction of HIV/AIDS.
Thus, the proposed study will enable the PI to contribute towards the provision of scientific basis for evaluating if the practice of widow inheritance is a risk factor for HIV acquisition; a contribution that will guide interventions targeting behavior change towards this cultural practice.

Co-investigators:
Professor Noel Weiss (MD, Dr.PH)) is a professor of Epidemiology at the University of Washington. He will be the overall mentor of the study and advise particularly on the study deign and/or matters of training project staff to carry out their respective duties, adherence to protocol during fieldwork, data management and analysis, and manuscript preparation. Professor Weiss was also the chair to the PI's MPH thesis on male circumcision and HIV- 1 among the Luo community and is thus conversant with many of the cultural issues of the Luo community. In addition, he has taught in the MPH programs both at Kenyatta University and at the University of Zimbabwe. He will provide advise mainly via e-mail and will also make one visit to Kenya at the start of the study to oversee the setting up, including the training of the study staff and the initial recruitment of study participants.

Professor Ann Vanderstoep (PhD) is an Associate Professor of Epidemiology and Mental Health at the University of Washington. She was an advisor of the PI in her PhD program and was instrumental during the development of the study protocol on widow inheritance among the Luo community. She provided continuous advice via e-mail during the fieldwork as well as on-site advice during dissertation preparation. She is thus well versed with issues around the cultural practice that the study is proposing to focus on. She will provide advice via e-mail and also make periodic field visits to monitor the study progress.

Mr. Billy A. Obare (BA, Hons, MA, Sociology of the University of Nairobi) is a long-time lecturer at Moi University in several Sociology courses, with a bias towards Methods of Social Investigation. He was the Field Coordinator for the PI during her studies on widow inheritance and male circumcision among the Luo. His duties included, among other tasks, mobilizing the participants to join the study, conducting in-depth interviews, and facilitating focus group discussions. He has since resigned from Moi University to start a research consultancy in Kisumu, *Impact Research and Development Consultancy*, where the proposed study will be headquartered. Under the aegis of the same consultancy, he is presently the field coordinator in an HIV-male circumcision evaluation study in Siaya District. Because the PI will devote 50% of her time in the project, Mr. Obare will be the Project Coordinator and as a social scientist who is also from the Luo community, he will be responsible for the day-to-day running of the project when the PI is away on duty at the UNIM project.

Mr. Ahenda (H.N.D, Medical Microbiology) is the Chief Laboratory Technologist with the UNIM Project on Reproductive Health currently being carried out in Kisumu. Prior to UNIM, he worked for the Walter Reed Program of the United States Army, also as the Chief Laboratory Technologist. In these two projects, Mr. Ahenda has been responsible for, among other things, investigation of the immune response in HIV/STI and characterization of markers of sexual activities of the study participants. Some of the techniques relevant to the proposed study that he has used in his vast experience include virus culture and isolation, viral genotyping by sequencing, Cytotoxic Lymphocyte Assays, Polymerase Chain Reaction. (P.C.R.), viral load assays, Reverse Transcriptas Polymerase Chain Reaction (RT-PCR), viral culture, and Immunophenotyping by Flow Cytometry e.g. CD4/CD8, NK counts. In the proposed project, he will be responsible for all the lab processes, from specimen collection to storage and transportation to Kisumu, as well as the ones to be taken to Nairobi. He will also be in charge of all the lab analyses at the central lab in Kisumu, procuring of the necessary equipment and supplies, and compiling of results from Kisumu and Nairobi and relaying then to the PI and the Field Coordinator to be returned to the study sites. He will work with Dr Bukusi to ensure that the Clinical Officers and Nurse-Counselors are adequately trained in taking and storing specimens and in carrying out rapid HIV tests (the initial training and period supervisory support will be done by CDC), as well as in keeping records of specimens collected. He will liaise with Prof. Ndinya-Achola regarding the analyses at the University of Nairobi.

Professor Jeckoniah Ndinya-Achola (MBChB, MSc) is currently the Dean of the Faculty of Medicine at the University of Nairobi. He is a professor of medical microbiology and has an extensive experience in national and international HIV/AIDS research in Kenya. Currently, he is involved with the UNIM project as a Co-PI, the HIV Vaccine Trial between the Universities of Oxford and Nairobi as a Co-Investigator, and several studies under a collaborative research between the University of Washington's International AIDS Research and Training Program (IARTP) and the University of Nairobi. In this collaboration, he is in the Executive Committee. Prof. Ndinya-Achola was also the filed advisor of the PI during her MPH and PhD fieldwork in Kenya. He will oversee both specimens collection, storage, transportation, and analysis both in Nairobi and in Kisumu where he will monitor periodically the activities carried out by Mr Ahenda and the field staff.

Dr. Elizabeth Bukusi (MD, MMed, [Ob/Gyn], MPH, PhD candidate at the University of Washington) is an experienced obstetrician and gynecologist and a researcher in women's reproductive health issues in Kenya. She is currently a faculty at the University of Nairobi and the Kenya Medical Research Institute. She will oversee the clinical components of the study, namely, performing medical examinations, taking specimens, making diagnoses and providing treatment. She will thus train the Clinical Officers and the Nurse-Counselors on these activities, supervise the initial performance, and make 4-day visits every month for the first 6 months, then quarterly for the remaining study period to monitor the performance of the clinical staff and attend to clients who may need specialized gynecological attention.

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

RESEARCH GRANT

TABLE OF CONTENTS

(Items A-D: not to exceed 25 pages)*
** SBIR/STTR Phase I: Items A-D limited to 15 pages*

Appendix *(Five collated sets. No page numbering necessary for Appendix.)*

Check if Appendix is Included ☒

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.

Number of publications and manuscripts accepted for publication *(not to exceed 10)* _____

Other items (list):

1. Study Forms (Consent Form, Questionnaires, etc):
2. Management of Sexually Transmitted Infections
3. PI's MPH and PhD Abstracts

BUDGET JUSTIFICATION PAGE MODULAR RESEARCH GRANT APPLICATION				
Initial Budget Period	Second Year of Support	Third Year of Support	Fourth Year of Support	Fifth Year of Support
$ 50,000	$ 50,000	$ 50,000	$ 50,000	$ 50,000
Total Direct Costs Requested for Entire Project Period				$ 250,000

Personnel

[redacted], PhD, MPH, Principal Investigator, (50% effort) will be responsible for the overall supervision of the study including recruitment and training of the personnel, adherence to the ethical and methodological details throughout and analysis of data and manuscript writing.

Noel Weiss, MD, Dr.PH., Co-investigator, (8% effort) will be the overall mentor of the study and advice particularly on matters of training project staff to carry out their respective duties, adherence to protocol during field work, data management and analysis and manuscript preparation.

Ann Vanderstoep, PhD., Co-investigator, (10% effort) will be mentor and provide advice and monitor the extent to which study personnel are going by the stated protocol. She will also advice on statistical analysis

Billy Obare, BA., MA., Co-investigator (100% effort) will be the project coordinator responsible for the day-to-day running of the project when the PI and co-investigators are away.

Hannington Obote Ahenda, HND., Medical Microbiology, Co-investigator, (25% effort) will be responsible for all the laboratory processes, from specimen collection to storage and transportation to the central laboratory in Kisumu and Nairobi. He will be in charge of all the laboratory analyses in Kisumu, procuring of the necessary laboratory equipment and supplies, and compiling of results from Kisumu and Nairobi and relaying them to the PI and field coordinator to be returned to the study sites. He will also participate in training Cos and nurse-counselors in taking and storing specimens and carrying out rapid HIV tests.

J.O. Ndiya-Achola, MBChB, MSc, Co-investigator (30% effort) will be the overall specialist for specimen collection, storage, transportation, and analysis both in Nairobi and Kisumu where periodically he will monitor the activities carried out by Mr. Ahenda and the field staff.

Elizabeth Bukusi, MBChB, Mmed (Obs/Gyn). MPH, PhC., Co-investigator (30%) will oversee the clinical components of the study eg performing medical examinations, taking specimens, making diagnoses and providing treatment. She will train the COs and the nurse-counselors on these activities and also periodically attend to clients who may need specialized gynecological attention.

To be appointed **Biostatician,** (20% effort) will be in charge of data at all stages. She/he will ensure the quality of the data being collected, oversee data entry and undertake data analysis. She will give advice on the data throughout the study.

To be appointed **2 female Clinical Officers,** (100% effort each), will carry out the clinical details of the study eg medical examinations, taking specimens like swabs, etc, making diagnoses and providing treatment at the two study sites.

To be appointed **2 female Nurse/Counselors,** (100% effort each), will provide the nursing care at the two study sites, like, dressing wounds, counseling services to clients, taking of specimen eg blood samples and administering behavioral questionnaires.

To be appointed **Assistant Laboratory Technician**, (100% effort) will assist the Chief Laboratory Technician above, in the laboratory processes - collection, transportation, storage of specimen and eventually conducting all laboratory analyses.

The **Laboratory Technician** at the department of Microbiology, University of Nairobi (10% effort) will carry out the lab processes that the central lab in Kisumu cannot do like where the double rapid HIV test yield discordant results and an Elisa is needed which can only be done in Nairobi.

To be appointed **Data Entry Clerk** (100% effort) will enter into the computer all the data that comes from the behavioral interview schedule, medical exams, HIV results, etc. on a daily basis as the data comes.

To be appointed **Secretary/Typist/Accounts Clerk** (100% effort) to do all the secretarial and typing duties and also, do and keep the project's account books. This will be at the Kisumu office where she will also be in charge of the general office administration.

To be appointed **2 Receptionists/Clerks** (100% effort) will be the front office persons at the two study sites to welcome clients, process them for the Cos and nurses, keeping of records and files as well as simple site administration, keeping the site clean, etc.

To be appointed **Driver** (100% effort) will be the one to transport specimen from the field site offices to Kisumu and also to take supplies to the field.

Consortium

The Department of Medical Microbiology, University of Nairobi (8% F & A per year)

Fee (SBIR/STTR Only)

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	Assistant Professor of Geography Project Coordinator, Geography

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Uppsala University	Diploma	1994	Human Nutrition
University of Nairobi, Nairobi, Kenya	Bed	1984	Education & Geography
Moi University, Eldoret, Kenya	MPhil	1991	Medical Geography
University of Washington, Seattle	MPH	2001	Epidemiology
University of Washington, Seattle	PhD	2001	Medical Geography

A: Education, Positions and Honors:

Educational background:

Dec 2001: Basic Skills in Voluntary Counseling and Testing of HIV, Centers for Disease Control and Prevention (CDC), Kisumu Station, Kenya

1996-2001: Ph.D. in Medical Geography, University of Washington
- Dissertation topic: Widow Inheritance and HIV/AIDS Interventions in sub-Saharan Africa: Contrasting Conceptualizations of 'Risk' and 'Vulnerability'—Conducted among the Luo ethnic community in Kenya.

1997-2001: MPH in Epidemiology, University of Washington
- Thesis topic: The Prevalence of HIV-1 in Rural Kenya: Association with Male Circumcision—Conducted among the Luo ethnic community.

1997-2001: Certificate in International AIDS Research and Training Program (IARTP), School of Public Health and Community Medicine, University of Washington.

1997-2001: Certificate in International Health Program (IHP), School of Public Health and Community Medicine, University of Washington.

1994: Postgraduate Diploma in Human Nutrition, Department of Nutrition, Uppsala University, Sweden
- Focus: Assessment of Nutritional Problems in Developing Countries

1994: Certificate in Community Nutrition Assessment Methods, Department of International Child Health, Uppsala University, Sweden.

1994: Certificate in Evaluation Methods in Health Care in Developing Countries, Department of International Child Health, Uppsala University, Sweden

1989-1991: Master of Philosophy in Medical Geography, Moi University, Kenya
- Thesis topic: Factors affecting Household Food Security in Siaya District, Kenya.

1980-1984: Bachelor of Education (Geography), University of Nairobi, Kenya

Professional experience:

June 1992 to 2001: Assistant Professor of Medical Geography, Moi University, Kenya

2001- Present Project Coordinator, UNIM Project—A University of Nairobi, Illiniois and Manitoba Collaborative HIV Research on Reproductive Health in Kisumu District, Kenya. The project is a Randomized Controlled Trial of Male Circumcision and HIV Infection.

Main duties:
- Ensure that all project activities are carried out according to the protocol.
- Keep in safe custody all information containing identities of participants.

- Coordinate the recruitment of participants into the study according to the procedures laid out in the protocol; ensure that subjects who do not return for follow-up visits are traced.
- Ensure that research funds are used according to the study budget and that reimbursements of study-related expenses are done promptly and efficiently.
- Submit progress report to the Principal Investigators and the Co-Investigators at required intervals.

From January 2002: Adjunct Faculty, The Tropical Institute of Community Health and Development (TICH) in Africa, Kisumu--supervising fieldwork and thesis for Master of Science students in Community Health and Development (One student every semester).

Summer 2001: Instructor, The Geography of Health and Health Care course, University of Washington

Winter 2001: Teaching Assistant, Population and Health, Univ. of Washington

1998-99; 2000: Teaching Assistant, Human Geography, University of Washington

1998: Program Evaluator, 1997-98 Greater Seattle Americorps Program.

1989: Lecturer, Kisii Teachers' Training College, Kenya (Trainer of High School Diploma Teachers)

1984-1988: Lecturer and Head of Social Science Department, Shanzu Teachers' Training College, Kenya (Trainer of Primary School Teachers)

2001: Arch Gerlach Dissertation Fellowship Award, University of Washington.

B: Publications:

2000: Effects of the Home and School Environments on the Development of Spatial Interaction in Kenyan Children: A Gender-Focused Study. *Journal of the Geographical Association of Tanzania* 29:107-120.

1997 Book Review. *The African Inheritance* by Ieuan LL Grifith. In *The Professional Geographer* 49(3): 380-381, August, 1997

1995 Ethnomedical remedies and therapies in maternal and child health among the Luo of Rural Kenya. In *Traditional Medicine in Africa*, edited by Isaac Sindiga, Chacha Nyaigoti-Chacha, with M.P. Kanunah. East African Educational Publishers, Nairobi.

1994 Impediments to achieving health for all in rural Kenya by the year 2000: Indicators from Nyanza Province. *African Journal of Health Sciences*, 1(4):51-7

Abstracts:

June 2001: HIV-1 in rural Kenya: A Comparison of Circumcised and Uncircumcised Men from African Independent Churches. Presented at the International Congress of Sexually Transmitted Infections, June 24-27, 2001, Berlin.

Feb/Mar '01: HIV/AIDS in sub-Saharan Africa: re-constructing 'spaces of vulnerability' within the framework of widow inheritance. Presented at the Association of American Geographers, Annual National Conference, February 27 – March 3, 2001, New York.

Oct. 1996: African culture and reproductive health: are women empowered to negotiate safe sex? Presented at the Association of Third World Studies Conference the University of Montgomery, Alabama.

Aug. 1996: The impact of polygyny, widow inheritance, and migration on AIDS transmission in rural Kenya. Presented at the Association of Anthropologists of Southern Africa Conference, the University of South Africa, Pretoria.

Aug. 1996: Vanishing borders in sub-Saharan Africa: Achievements, counterforces, and prospects. Presented at the Commonwealth Geographical Bureau Conference, the University of Malaya, Malaysia.

April 1995: Gender and the use of environment in teaching Geography. Presented at the Commonwealth Geographical Bureau Conference on Geography and Gender, the University of Amsterdam, The Netherlands.

Feb. 1995: Widow inheritance and AIDS transmission in Kenya: preliminary considerations. Presented at the African Health Sciences Congress, Kenya Medical Research Institute, Nairobi.

C: Research awards and fellowships:

2002-03: Co-Principal Investigator of a research study entitled: "Male Circumcision in Siaya District: A Prospective Cohort Study to assess sexual behavior of clients before and after circumcision". The study is an evaluation of an on-going project called: "Integration of Male Circumcision Practice in Reproductive Health Programs in Nyanza Province" sponsored by the Belgian Government.

1999-00: Principal Investigator of a study entitled: "Is Male Circumcision Associated with HIV Infection: A Cross-Sectional Study among the Luo in Rural Kenya" The study was towards my MPH thesis and was

supported by the International AIDS Research and Training Fellowship (Fogarty International/National Institutes of Health).

1999-00: Principal Investigator of a study entitled: "HIV/AIDS and Widow Inheritance in Nyanza Province: What do the Practitioners say?" The study was towards my PhD in Medical Geography and was supported by The Population Council Fellowship.

1998-01: Philanthropic and Educational Organization, International Peace Scholarship. The Scholarship provided financial support towards books and subsistence during graduate study in the U.S.

1996-98: The Fulbright Junior Staff Development Fellowship, United States Information Agency. This was a Competitive Fellowship awarded to pursue PhD studies at the University of Washington, USA.

1995-96: The Robert S. McNamara Fellowship Program of the World Bank for research on AIDS education in Nyanza Province (The Fellowship was later withdrawn due to degree in progress).

1995-96: The 7th Research Competition on Gender Issues from the Organization for Social Science Research in Eastern and Southern Africa (OSSREA) for research on AIDS and selected cultural practices of the Luo community

1995-96: Association for African Women in Research and Development (AAWORD) award for research on the Inhibitors to family planning adoption in Siaya District, Nyanza Province, Kenya.

1994: The Swedish Institute Fellowship for a Diploma course in Nutrition in Developing Countries at Uppsala University, Sweden. Two Certificate courses in Public Health Methodology also taken during the same period.

1992: Impediments to achieving Health for All by the year 2000: Indicators from Nyanza Province, Kenya – funded by self.

1990-91: Physical and socioeconomic factors affecting Household Food Security: The case study of Siaya District, Kenya. Funded by the Government of Kenya (for my M.Phil. thesis, Moi University)

Membership to professional organizations:

Since 1994: The Association for African Women in Research and Development (AAWORD)

Since 1995: The Organization for Social Science Research in Eastern and Southern Africa (OSSREA).

Since 1998: Association of Third World Studies (ATWS)

Volunteer work:

Since 1996: Founder and Director, Ushindi Children's and Widow's Support Services

Since 2000: Member, Barchando Widow's and AIDS Welfare Group

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Hannington Ahenda	Chief Laboratory Technologist

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
Mombasa Polytechnic	Diploma	1989	Medical Lab. Technology
Mombasa Polytechnic	Higher Nat. Diploma	1999	Medical Microbiology

A: Education, Positions and Honors:

2001: Certificate course in Good Laboratory Practice and Good Clinical Practice sponsored by US Military HIV Program and facilitated by USA Food and Drug Administration Regulatory Affairs Committee, Kericho, Kenya.
2001: Head of delegation of Walter Reed Program-Kericho Station to the Uganda Virus Research Institute, Entebbe, the Joint Clinical Research Centre, and the Henry M. Jackson & WRP Laboratories in Mulago Hospital in Kampala, Uganda. The purpose of the visit was to learn from the HIV research activities in Rakai District (Rakai Project).
2000: Certificate Counseling Skills
1997-1999: Higher National Diploma Course; Mombasa Polytechnic (Medical Microbiology, Molecular Biology, Immunology, Statistics and Management)
1986 – 1989: Diploma in Applied Sciences, Mombasa Polytechnic (Medical Laboratory Technology Option)
1980 –1983: Usenge High School, Kenya Certificate of Secondary Education

WORK AND RESEARCH EXPERIENCE.

Jan. 2002 to date: Chief Laboratory Technologist and Head of Logistics, UNIM Project. The project is carrying out a Randomized Controlled Trial of Male Circumcision to reduce HIV incidence in Kisumu, Kenya, under Prof. Robert Bailey (University of Illinois at Chicago) as the Principal Invesstigatos, Dr. Steven Moses (University of Manitoba), Prof J.O Ndinya-Achola (Medical Microbiology, University of Nairobi), among others, as the Co-Investigators.

- Main duties:
  - Investigating the immune responses in circumcised and non-circumcised subjects.
  - Investigating the immune response in HIV/STI.
  - Quantification of HIV receptors on the foreskin of circumcised subjects.
  - Characterization of markers of sexual activities in the 18-24 males in Kisumu.

January 2001-January 2002.

- Chief Lab Tech: HIV and Malaria Programme in Kericho, under Walter Reed Program of the US Army
- **Main duties:**
  - Investigating the HIV subtypes in transmission in Kenya.
  - Cohort Studies -: Comparison of the virology and Immunology of HIV subtypes HIV-1 and HIV-2 and relating these to progression of disease in clinical Cohorts of defined number of subjects.
  - Investigation of cellular immune responses in HIV co-infection with Malaria.
  - Investigations of Chemokine Receptor Expression in HIV infections.
- **Techniques used.**
  - Virus culture and isolation.
  - Viral genotyping by sequencing.
  - Cytotoxic Lymphocyte Assays.

- Polymerase Chain Reaction. (P.C.R.)
- Viral load Assays.
- Reverse Transcriptas Polymerase Chain Reaction. (RT-PCR)
- Viral culture.
- Immunophenotyping by Flow Cytometry e.g. CD4/CD8, NK counts.
- Parasite/Tissue Culture.

January 2000 to August 2000.

- Chief Lab Tech: Investigation of cellular responses in HIV and Schistosomiasis co-infections on a cohort of Fishermen and Carwashes in Kisumu town. A Program of the Kenya Medical Research Institute, Centre for Vector Biology and Control Research- Kisumu, and Centers for Disease Control and Prevention (CDC) Schistosomiasis & HIV Program
- **Main duties:**
  - Determination of the efficiency of PZQ in treatment of Schistomiasis in patients co-infected with HIV.
  - Kinetics of Cytokine production in HIV/ Schistomiasis Co- infections.
  - Chemokine Receptor expression in HIV/Schisto Co-infections
- Methods.
  - Viral cultures and cell infections.
  - Viral load determination by protein24 ELSA.Determination of pre and post treatment levels by Circulating Cathodic Antigen ELISA.
  - Flow Cytometry analysis.
  - Proliferation Assays.

January 1997 to February 1998.
U.S Army Medical Research Unit/ KEMRI, Malaria Vaccine Program.

- **Main Duties:**
  - Determination of HLA prevalence's amongst malaria infected individuals in Western Kenya.
  - Investigating the Role of Agglutination and Anti-Adhesion antibodies in malaria infected people in Western Kenya.
  - Determining the binding affinity of P.falciparum to various Venular Endothelial Molecules eg CD36,TSP,CSA,ICAM-1,and VCAM and relating these to clinical manifestations of malaria.
  - Investigating the binding affinity of P.falciparum in pregnancy to Chondroitin Sulphate-A.
  - Gene expression studies in clinical manifestation of malaria.
  - Representations Differences Analysis of subtypes of P.falciparum responsible for various clinical manifestations.
  - P.falciparum Gene Library Construction by use of Complementary DNA (cDNA)
- **Methods**
  - Parasite (Tissue culture)
  - Binding Assays.
  - Agglutination Assays.
  - Reverse Transcriptase PCR (RT-PCR).
  - RDA-PCR by mRNA isolation and purification
  - HLA typing

Jan.1994-Dec.1996.

Senior Lab Technologist: Wellcome Trust Research Laboratories/KEMRI (Centre for Geographic Medicine and Research –Coast Kilifi project-)--Epidemiology of Community Acquired Pneumonia.

- **Main Duties:**
  - .Evaluation Of Conventional Microbiological Methods used for isolation and establishing diagnosis of pneumococcal pneumonia
  - .Epidemiology and Microbiology of Penicillin Resistant S.pneumoniae.
  - .Determination of Drug Susceptibility/Resistance of S.pneumoniae.

- The role of hormonal imbalances in HIV, M.tuberculosis and S.pneumoniae infections.
- Determination of Pneumococcal Serotypes in transmission in Coast Province.
- Bioassays in body fluids.

- **Methods used:**
  - Quellungs Reaction
  - E-Test Strip Technique for MIC determination
  - Blood,Lung Aspirate,Sputum & NPS cultures.
  - Complement Fixation Tests.
  - Mycobacteria cultures and drug sensitivities.
  - Agglutination Assays (Urine Antigen Detection Assays).
  - HIV ELISA and Western Blot.
  - Mycoplasma and Legionella pneumophilia Particle Agglutination Assays.
  - General Hematology and Biochemistry methods.

Jan 1992-Dec 1993.

- **Lab Techonoligist:** Port Reitz Maternity Hospital.
- **Main Duties:**
  - General Diagnostic Laboratory Duties.
  - Administrative Duties-: staff supervision, inventory control,purchasing and allocation of duties and responsibilities.

Jan 1991-Dec 1992

Laboratory Technologist: Malaria, Anaemia and Salmonellosis in Children in Siaya District, a Project of the Centers for Disease Control and Prevention/Kenya Medical Research Institute, Centre for Vector Biology and Control Research-Kisumu (Principal Investigators: Dr. Eve Lackritz and Dr. Jane Zucker)

- **Main Duties:**
  - Setting-up a Microbiology Lab.and taking responsibility for management.
  - Culture,isolation, identification and performance of sensitivity tests on isolates.
  - Inventory control.
  - Logistics

Publications.

Ahenda HO: Development of Urine Antigen Detection Technique for Diagnosis of Pneumococcal pneumonia in Kenya.(Dissertation presented to the Kenya Examination Council for the award of Higher National Diploma in Applied Sciences Microbiology, Molecular Biology, Immunology, Statistics & Management Option)by the Mombasa Polytechnic/KNEC,NOV/DEC examination series, 1999.

Ahenda HO, Jag Scott & K. Marsh Evaluation of Latex Agglutination Technique for diagnosis of pneumococcal pneumonia in epidemiological studies in Kenya. *Journal of Infectious Diseases* Jan.99

Ahenda HO, Jag Scott & K. Marsh
Pneumococcal Serotype distribution at the Kenya Coast and the epidemiology of Penicillin Resistant pneuomococci in Kilifi Hospital. *Journal of Infectious Diseases Jan.99*

P. Mwinzi, **H.O Ahenda**, DMS Karanja, E. Secor
Investigation of Cellular Immune Responses in Schistosomiasis Co-Infection with HIV.

Ahenda HO, Duffy P., Michal F.
Appearance of Agglutinating Antibodies and Anti-Adhesion Antibodies in the blood of P.falciparum infected people living in malaria endemic Area of Western Kenya

Duffy P., **Ahenda HO.**, Opiyo M., Gitonga J.
P.falciparum in Western Kenya-: Agglutination, Adhesion, and the var Gene

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
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NAME	POSITION TITLE
Elizabeth A. Bukusi	Research Officer (Kenya Medical Research Institute); Honorary Lecturer (University of Nairobi)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Nairobi, Nairobi, Kenya	MBChB	1981	Medicine
University of Nairobi, Nairobi, Kenya	MMed	1990	Obstetrics & Gynaecology
University of Washington, Seattle	MPH	2000	Epidemiology
University of Washington, Seattle	PhD (C)	2001-Pres	Epidemiology

A: Positions and Honors:

1. Internship 1987-1988 Kenyatta National Hospital, Nairobi, Kenya.
2. Medical Officer, Ministry of Health, Busia District Hospital 1988-1990.
3. Assistant Research Officer Kenya Medical Research Institute, Center for Microbiology Research 1990-1995.
4. Senior House Officer in the Department of Obstetrics and Gynecology, University of Nairobi, Kenya. 1990-1995.
5. Research Officer, Kenya Medical Research Institute (KEMRI), Center for Microbiology Research, Sexually Transmitted Disease from 1995 to date.

Other professional positions

1. Honorary lecturer and Senior Registrar in the Department of Obstetric and Gynecology, University of Nairobi March 1995 to date.
2. Research Physician, WHO Collaborative project, University of Nairobi, Department of Medical Microbiology from April 1995 to date.
3. Coordinator for the Clinical Care guidelines in the Era of HIV, University of Nairobi, Departments of Medical Microbiology and Community Health in collaboration with CIDA and the Belgian project on Strengthening STD control in Kenya. (NASCOP) September 1996- July 1997. Product: Manual for the clinicians to use in management of common conditions in areas of high prevalence when testing for HIV not consistently available.
4. Practicum experience with Christian Health Association of Kenya as Programs Manager from September 1998 August 2000. Headed programs department including supervision of training and MIS officers. Was Editor to CHAK Times, a quarterly publication of the institution. Provided technical support to CHAK units and supervised the implementation of programs including AVSC and initiated a post abortion care program in selected sites in CHAK. Organized the Annual general meeting 1999.

Honors:

1. FIGO FELLOWSHIP COPENHAGEN 97.
2. Poster presentation on "The impact of HIV-1 on Pelvic inflammatory disease in an outpatient clinic in Nairobi, Kenya." For this poster the following awards were given:
   i. Runner up in the infectious disease category, Upjohn Young female scientist's award.
   ii. Among the 10 best posters for the Wednesday poster presentations

Professional societies:

1. Kenya Medical Association (served on the MEDICUS, editorial and standing committees, 1997-1999 and on the Tobacco Control Committee from 1998 to date)
2. Kenya Obstetric and Gynecological Society (served as Committee member 1995-1997 and Assistant Secretary 1997-1999)

3. Christian Medical Fellowship
4. Kenya Association of University Women.
5. Kenya Medical Women's Association

B: Selected publications:

1. **Bukusi E**, Cohen C R, Stevens C, Sinei S, Reilly M, Greico V, Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, Moses S, Kreiss J K. Outpatient diagnosis and treatment of pelvic inflammatory disease among women with a high HIV-1 seroprevalence in Nairobi, Kenya. **Am J Obstet Gynecol . 2000 Jan;98(1): 72-7.**
2. Cohen C R, Sinei S, **Bukusi E**, Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, Karanja J, Kreiss J K. Effect of Human immunodeficiency virus type 1 infection upon acute salpingitis: a laparoscopic study. **JID 1998; 178; 1352-8.**
3. Cohen C R, Plummer FA, Mugo N, Maclean I, Shen C, **Bukusi E**, Irungu I, Sinei S, Bwayo J and Brunham R. Increased Interleukin- 10 in the endocervical secretion of women with non ulcerative sexually transmitted diseases: a mechanism for enhanced HIV-1 transmission? **AIDS 1999,13:327-332.**
4. Cohen C R, Gaur L, MacDonald K, **Bukusi E**, Sinei S, Holmes K, Kreiss J, Bwayo J, Brunham R. MHC class I and II allelic association with *Chlamydia trachomatis* serostatus among women with tubal factor infertility in Nairobi Kenya. **Obstet Gynecol 2000 Jan;95(1)**
5. Craig R. Cohen, Rosemary Nguti, **Elizabeth A. Bukusi**, Hang Lu, Caixia Shen, Ma Luo, Samuel Sinei, Frank Plummer, Job Bwayo Robert C. Brunham. Human immunodeficiency virus type 1-infected women exhibit reduced interferon-gamma secretion after Chlamydia trachomatis stimulation of peripheral blood lymphocytes. **J Infect Dis. 2000 Dec;182(6):1672-7**
6. Baeten J M, **Bukusi E A**, Lambe M. AJPH Pregnancy Complications and Outcomes Among Overweight and Obese Nulliparous Women. **Am J Public Health. 2001 Mar;91(3):436-40**
7. Cohen C R, Sinei S, Reilly M, **Bukusi E**, Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, Karanja J, Kreiss J. Demonstration of *Chlamydia trachomatis* in endometrial and Fallopian tube tissue among women with tubal infertility in Kenya. Kenya. **Manuscript in progress**
8. Cohen C R, Sinei S, **Bukusi E**, Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, Karanja, J, Kreiss J. Pregnancy rate after laparoscopic tuboplasty for tubal factor infertility in Nairobi, Kenya. **Manuscript in progress**
9. Cohen C R, Sinei S, **Bukusi E**, Stamm W, Eschenbach D, Holmes K, Ndinya-Achola, JO, Kreiss J, Karanja, J, Brunham R. Cytockine m-RNA detection in endometrial and Fallopian tube tissue among women with acute pelvic inflammatory disease and tubal factor infertility. **Manuscript in progress**.
10. **Bukusi E A**, Cohen C R, Karanja J G, Waiyaki PW, Bwayo J, Eschenbach D , Kreiss J K, Holmes KK . Bacterial Vaginosis: The Male factor **Manuscript in progress**
11. **Bukusi, E A**, Craig R. Cohen, Rosemary Nguti, Jane N. Mungai, Job J. Bwayo, Peter W. Waiyaki, Joseph G. Karanja, King K. Holmes ACCURACY OF THE 'FemExam®' RAPID DIAGNOSTIC TEST TO DIAGNOSE BACTERIAL VAGINOSIS. **Manuscript in progress**
12. **Bukusi E A**, Sinei S, Cohen C R. High Acceptability Of HIV-1 Testing Among Infertile Couples Attending a Refferal Infertility Clinic in Nairobi, Kenya. **Manuscript in progress**

Abstracts

1. Malonza I, Tyndall M, Hawken M, **Bukusi E**, MacDonald K, Maclean I, Perriens J, Ronald AR, Ndinya Achola J O, Moses S. Randomized, double blind, placebo controlled clinical trial of erythromycin and ciproflaxacin in the treatment of chancroid. XI International conference on AIDS, Vancouver, Canada, 1996.
2. Cohen C R, Sinei S, **Bukusi E,** Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, Karanja J, Kreiss J K. Effect of HIV-1 infection upon acute salpingitis: a laparoscopic study in Kenya (Abstract 113) XI International conference on AIDS, Vancouver, Canada, 1996.
3. **Bukusi E**, Cohen C R , Stevens C, Sinei S, Reilly M, Greico V , Stamm W, Eschenbach D, Holmes K, Ndinya-Achola JO, .Moses S, Kreiss J K. The impact of HIV-1 on Pelvic Inflammatory Disease in an outpatient clinic in Nairobi, Kenya. FIGO conference, Copenhagen , Denmark August 1997.
4. **Bukusi E A** [1,2],Cohen C R, Karanja J G, Waiyaki PW, Bwayo J, Eschenbach D , Kreiss J K, Holmes KK . Bacterial Vaginosis: Evidence For Sexual Transmission and Association With HIV-1. XIII World AIDs conference Durban, South Africa.

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Jeckoniah O. Ndinya-Achola	Associate Professor of Medical Microbiology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
University of Nairobi, Nairobi, Kenya	MBMChB	1974	Medicine
University of Qeensland	CMPl	1975	Medical Microbiology
University of London	MSc	1981	Medical Microbiology

A: Positions and Honors

2001-Present: Ag. Dean, School of Medicine, University of Nairobi.
1995 to date: Associate Professor, Department of Medical Microbiology
1985 to 1996: Honorary Consultant, Microbiologist, Kenyatta National Hospital Nairobi
1990 to 1996: Chairman, Department of Medical Microbiology
1985 to 1995: Senior Lecturer, Department of Medical Microbiology University of Nairobi
1976 to 1981: Assistant Lecturer, Department of Pathology, University of Nairobi Registrar in Pathology, Kenyatta National Hospital
1975: Medical Officer, Kenyatta National Hospital
1974 to 1975: Medical Officer, Intern, Kenyatta National Hospital
1980 to 1981: Hon. Registrar, in Microbiology, Royal Postgraguate Medical School London
1982 to 1985: Hon. Senior Registrar Kenyatta National Hospital
1989 to 1999: Visiting Research Scientist University of Washington, Seattle, U.S.A.

Other Responsibilities

1985 to 1996: Director/Scientific Coordinator, WHO Collaborative Center for Sexually Transmitted Disease Research and Training
1985 to 1990: Member, Kenyatta National Hospital Infection Control Committee
1986 to 1990: Member, Kenya National AIDS Control Program And Chairman of its Laboratory Sub-committee
1990 to 1994: Chairman, Kenya National AIDS Control Program
1987 to date: Member Programs Committee, Kenya Medical Research Institute Programs Committee in Sexually Transmitted Disease and AIDS Program

B: Selected Peer-Reviewed papers (since 1995, out of 140 articles)

1. Anzala AO, Nagelkerke JD, Bwayo JJ, Holton D, Moses S, Ngugi EN, **Ndinya-Achola JO**, Plummer FA. Rapid progression to disease in African sex workers with human immunodeficiency virus type 1 infection. *J. Infect. Dis.* 171: 686 – 689, 1995.
2. Moses S, Plummer FA, Bradley JE, **Ndinya-Achola JO**, Nagelkerke NJD, Ronald AR Male Circumcision and the AIDS Epidemic in Africa *Health Transition Review* 5: 100-103, 1995.

3. Jackson DJ, Martin Jr, HL, Bwayo J, Nyange PM, Rakwar JP, Kashonga F, Mandalya K, **Ndinya-Achola JO**, Kresiss JK, Acceptability of HIV Vaccine Trials in High-Risk Heterosexual Cohorts in Mombasa, Kenya. *AIDS* 9: 1297 – 83 1995.
4. Jackson DJ, Rakwar JP, Chohan B, Mandalya K, Bwayo J, **Ndinya-Achola JO**, Nagelkerke NJD, Kreiss JK, Moses S. Urethrial Infection in a Workplace Population of East African Men: Evaluation of Strategies for screening and Management. *J. Inf. Dis.* 175: 833-8,1997.
5. Tyndal MW, Ronald AR, Agoki E, Malisa W, Bwayo JJ, **Ndinya-Achola JO**, Moses S, Plummer FA Increased Risk of infection with Human Immunodeficiency Virus Type 1 among Uncircumcised Men Presenting with Genital Ulcer Disease in Kenya *Clin. Inf. Dis* 23: 449 – 53 1996.
6. Margo CM, Crowson AN, Alfa M, Nath A, Ronald A, **Ndinya-Achola JO**, Nasio J A Morphological Study of Penile Chancroid Lesions in Human Immunodeficiency Virus (HIV) – Positive and - Negativr African Men with a hypothesis Concerning the Role of Chancroid in HIV Transmission. *Human Pathl.* 27: 1066 – 70, 1996.
7. MacDonald KS, Embree J, Njenga S, Nagelkerke NJD, Ngatia I, Mohammed Z, Barber BH, **Ndinya-Achola JO**, Bwayo J, Plummer FA. Mother –child Class I HLA Concordance Increased Perinatal Human Immunodeficiency Virus Type 1 Transmission. *Journ. Infe. Dis* 177: 551 – 6, 1998.
8. Martin Jr HL, Steven CE, Richardson BA, Rugamba D, Nyange PM, Mandalya K, **Ndinya –Achola JO**, Kreiss JK Safety of a Nonoxcynol-9 Vaginal Gel in Kenyan Prostitutes: A Randomized Clinical Trial. *Sex. Trans. Dis.* 24: 297 – 83, 1997.
9. Jackson DJ, Rakwar JP, Richardson BA, Mandalya K, Chohan BH, Bwayo J, **Ndinya-Achola JO,** Martin Jr HL, Moses S Kreiss JK. Decreased Incidence of Sexually Transmitted Diseases among Trucking Companies in Kenya: results of a Risk-Reduction Programme. *AIDS II*: 903 – 09, 1997
10. Rakwar J, Jackson D, Maclean I, Obongo T, Bwayo J, Smith H, Mandalya K, Moses S, **Ndinya-Achola JO**, Kreiss JK. Antibody to Haemophilus ducreyi Among Trucking Company Workers in Kenya *Sex. Trans. Dis* 24: 267-71
11. Mostad SB, Overbaugh J, DeVange DM, Welch MJ, Chohan B, Mandaliya K, Nyange P, Martin Jr. HL, **Ndinya-Achola JO**, Bwayo J, Kreiss JK. Hormonal Contraception, Vitamin A deficiency and other risk factors for shedding HIV- 1 infected cells from cervix and vagina *Lancet* 350: 922-7, 1997
12. **Ndinya-Achola JO**, Ghee AN, Kihara AN, Krone MR, Plummer FA, Fisher LD, Holmes KK. High HIV prevalence, low condom use and gender differences in sexual behaviour among patients with STD-related complaints at a Nairobi Primary Health Care Clinic International *Journal of STD and AIDS* 8: 506-14, 1997.
13. Rusen ID, Fraser-Roberts L, Slaney L, Ombette J, Lovgren M, Datta P, **Ndinya-Achola JO**, Talbot JA, Nagelkerkej, Plummer FA, Ebree JE. Nasopharyngeal pneumoccoccal colonization among Kenyan children: Antibiotic resistance, strain types and associations with Human Immunodeficiency virus type 1 infection. *Paediatric Infections Disease Journal* 16: 656-62, 1997
14. Poss M, Gosink j, Thomas E, Kreiss JK, **Ndinya-Achola JO**, Mandalya KL, Bwayo j, Overbaugh J Phylogenetic Evaluations of Kenyan HIV Typoe 1 Isolates. *AIDs Research and Human Retroviruses* 13: 493-99, 1997
15. Odhiambo FA, Murage EM, ngare W, **Ndinya-Achola JO** Detection rate of Cryptococcus neoformans in Cerebrospinal fluid specimens at Kenyatta National Hospital, Nairobi. *EAMJ* 74: 576-78, 1997
16. Omari MA, Malonza IM, Bwayo JJ, Mutere AN, Murage EM, Mwatha Ak, **Ndinya-Achola JO.** Pattern of bacterial infections and antimicrobial susceptibility at Kenyatta national Hospital, Nairobi Kenya. *EAMJ* 74: 134-7,1977
17. **Ndinya-Achola JO**, Omari MA, Odhiambo FA, Murage E, Mutere AN Survey of penicillin resistant pneumococci at Kenyatta Natioal Hospital, Nairobi. *EAMJ* 74: 151-3, 1997
18. Malonza IM, Omari MA, Bwayo JJ, Mwatha AK, Mutere AN, Murage EM, **Ndinya-Achola JO.** Community – acquired bacterial infections and their susceptibility in Nairobi *EAMJ* 74: 166-70, 1977
19. Gichangi Pb, **Ndinya-Achola JO**, Ombette J, Nagelkerke NJ, Temmerman M. Antimircobial prophylaxis in pregnancy: A randomized placebo-controlled trial with cefetamet – Pivoxil in pregnant women with a poor obstetric history. *Am. J. Obstet. Gynecol.* 177: 680-4, 1997
20. Van der Ploeg CPB, Van Vliet C, De Blas SJ, **Ndinya-Achola JO**, Fransen L, Van Oortmarssen GJ, Habbema JDF. *STDSIM: A Microsimulation Model for Decision Support in STD Control Interfaces* 28: 84-100, 1998.
21. Temmerman M, Kidula N, Tyndall M, Rukaria – Kaumbutho R, Muchiri L, **Ndinya-Achola JO.** The Supermarket for Women's Reproductive Health: The burden of genital infections in a family planning clinic in Nairobi, Kenya. *Sex. Trans. Inf* 74: 202 – 4, 1998.

22. Lavreys L, Thompson ML, Martin Jr HL, Mandaliya K, **Ndinya-Achola JO**, Bwayo JJ, Kreiss J. Primary Human Immunodeficiency Virus Type 1 Infection: Clinical Manifestations among Women in Mombasa, Kenya. *Clinical Infections Diseases* 30: 486-90, 2000-09-12
23. Fonck K, Kidula N, Jaoko W, Estambale B, Claeys P, **Ndinya- Achola JO**, Bwayo J, Temmerman M. Validity of the vaginal discharge algorithm among pregnant and non-pregnant women in Nairobi, Kenya. *Sex. Trans. Inf.* 76: 33-38, 2000

BIOGRAPHICAL SKETCH

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NAME	POSITION TITLE
Billy A. Obare	Deputy Director, Impact-Research & Development Consultancy

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
University of Nairobi, Nairobi, Kenya	BA (Hons)	1986	Sociology
University of Nairobi, Nairobi, Kenya	MA	1988	Urban & Regional Planning

WORK EXPERIENCE

1982 – 1983: Secondary School Teacher, Majiwa Secondary School
1990 – 1991: Tutorial Fellow, Sociology Department, Moi University
1991 – Nov. 2000: Lecturer, Sociology Department, Moi University

COURSES TAUGHT AT MOI UNIVERSITY:

1. Methods of Social Investigation/Research – Second/Third year course
2. Social Policy and Administration – Third year course
3. Planning and Development – Fourth year course
4. Principles of Social Work (co-taught) – fourth year course
5. Project Evaluation and Planning – Fourth year course
6. Urbanization in Africa – Fourth year course
7. Urban Anthropology (co-taught) – Fourth year course

RESPONSIBILITY AT MOI UNIVERSITY:

1991 – 1995: Representative of Sociology Department to the Research Committee of the School of Social, Cultural and Development Studies.

OTHER WORK EXPERIENCE:

1988 – 1990: Physical Planner, Forward Planning Section, Physical Planning Department, Ministry of Lands and Housing.

DUTY:
1. Overseeing the gathering and analysis of social, economic and physical data and preparation of the long-term (for 30 years) structure plan for Kakamega Municipality. I left the plan in first draft when I left the Civil Service in September 1990.
2. Member of the team overseeing and evaluating the progress in the preparation of other structure plans for Mombasa, Machakos, Kisii, Mbale Municipalities and Kabarnet Town. Mombasa and Kisii Plans were in their first drafts and the rest nearing completion when I left.

RESPONSIBILITIES IN THE CIVIL SERVICE:

1988 – 1990: Secretary to Forward Planner's Committee chaired by the Director of Physical Planning Department or Head of forward Planning Section.
1989 – 1990: Member of the Department shows preparation committee (For A.S.K. shows and other exhibitions).

RESEARCH EXPERIENCE AND PROPOSALS:

1985 – 1986:	Research assistant in the study "Technical Training and work experience in Kenya: A national Tracer Study of Leavers of Harambee institutes of Technology and Youth Polytechnics". Funded by DANIDA with Dr. Mauri Yambo as the Principal Investigator.
1985 – 1986:	"Client Acceptance of and Participation in Directed Development Projects in Bondo, Siaya District", Research for B.A. Hons. Thesis.
1986:	"Nyakumu Swamp Agro-Forestry study". Social, economic and Environmental impact assessment of the Agro-Forestry project.
1987:	Implementation breakdown in rural projects". Assessment and report on case rural development project implementation – North Sakwa Water Supply Project.
1987:	"Pumwani Urban Study", member of group assigned by the department of Urban and Regional Planning, University of Nairobi and the Nairobi City Commission to study and work out modalities for the re-development of Majengo slums in Pumwani. The report was accepted and recommendations adopted and implemented the same year to become the High-rise residential development in the area.
1987:	"Implementation of Kibera Human Development Project". Assessment and report on case urban development project implementation.
1987 – 1988:	"Kakamega District Study: An integrated District Development Plan" Member of the study team to gather data and draw the regional medium – term (10 year) plan with Kakamega District Development Committee as clients.
1987 – 1988:	"The Conflict between fishing and agricultural production activities: The Bondo case" - Research for M.A. thesis.
1989 – 1990:	"The Kakamega structure Plan", Social Economic and Physical data gathering, analysis and plan preparation for the Municipality.
1992:	"Housing the urban poor: Toward an ability – participation model for squatters and slum dwellers in Kenyan Towns" Seminar paper.
1993:	"Rural Resource – use conflicts: Household labor and capital allocation and their implications for integrated rural development among the Fishing Farmers of Lake Victoria's Hinterlands". Seminar Paper – Moi University, Sociology Department.
1994:	"Investment perception in Growth Centers in Kenya: A Focus on Rural-Urban Interface". Seminar paper – Moi University, Sociology Department.
1994/95:	Home and School Environments: Implications for Academic Achievement by Girls in primary schools. Co-authored Seminar paper – Moi University, Sociology Department.
1998 – 1999:	Developed the Bachelor of Arts (Sociology) Program for Maseno University to start the new Department. This involved designing 53 courses and the whole degree structure.
1999:	Resigned from Moi University to be a founder member of Impact Research and Development Consultants (Impact – RDC) as the Deputy Director.
1999 – 2000:	Under the aegis of Impact Research and Development Consultants, I was the Field Coordinator in Dr. Kawango's MPH thesis research study on male circumcision in Luo Nyanza as well as her PhD dissertation research on Widow inheritance among the Luo's.
2002 –	Under Impact – RDC I am currently a field coordinator in an HIV – male circumcision evaluation study in Siaya District.

ARTICLES and ABSTRACTS:

2002:	July 2002: HIV-1 in rural Kenya: A Comparison of Circumcised and Uncircumcised Men from African Independent Churches. Abstract to be presented at the World AIDS Conference, Barcelona.
2002:	June 2002: Querying the utility of 'risk analysis' in HIV interventions targeting cultural behavior change in sub-Saharan Africa. Abstract to be presented the Hawaii International Conference on Social Sciences, Honolulu.
1989:	"Problems of Urban Development". Article published in Architecture, the official *Journal of the Architectural Association of Kenya* (A.A.K.) Vol. II, No.3, May/June, 1989.

FF Principal Inestigator: AGOT, Kawango E

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Photocopy this page or follow this format for each person.

NAME	POSITION TITLE
Ann Vander Stoep	Assistant Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Stanford University	BA, w/ distinction	9/69-8/73	Human Biology
University of Oklahoma	MS	9/76-2/79	Epidemiology
Columbia University	Visiting Fellow	9/95-5/95	Psychiatric Epidemiology
University of Washington	Ph. D.	9/93-11/97	Epidemiology

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

Professional Experience

1972 *Research Assistant*, Gombe Stream Research Center, Tanzania, studied mother-infant behavior in wild chimpanzees (Jane Goodall, Ph.D., Principal Investigator).

1978 *Research Analyst*, State of Washington, studied effect of cluster living program on developmentally disabled adults (Sharon Landesman-Dwyer, Ph.D., Principal Investigator).

1979-80 *Staff Epidemiologist*, United States Agency for International Development, Dar es Salaam, Tanzania. *Project Design Coordinator*, Division of Community Medicine, University of Dar es Salaam, Tanzania, designed study of impact on health of World Bank sanitation project.

1981-86 *Research Assistant and Research Project Coordinator*, Seattle Children's Home, Seattle, WA.

1986-87 *Research Director*, Mental Health Service Utilization Study, Algarve, Portugal.

1987-94 *Research Director*, Seattle Children's Home.

1990-94 *Project Director*, statewide evaluation of treatment foster care and psychiatric residential treatment programs, Division of Mental Health, Olympia, WA.

1991-94 *Project Director*, evaluation of children's mental health services in King County, King County Mental Health Division, Seattle, WA.

1993-97 *Doctoral Student*, University of Washington, Department of Epidemiology. Doctoral Dissertation: "Transition to dulthood for Adolescents with Psychiatric Disorder" (Shirley Beresford, Ph.D., committee chair).

1994-96 *Instructor*, designed curriculum and taught graduate course in research methodology Northwest Institute of Acupuncture and Oriental Medicine, Seattle WA.

1995-97 *Teaching Assistant*, University of Washington, Department of Epidemiology and Columbia University, Division of Epidemiology.

1994-96 *Principal Investigator*, NIMH Grant, studied utilization of multiple service systems by children, and

1994-97	*SeniorResearch Investigator*, Seattle Children's Home, Seattle, WA. *Psychiatric Epidemiology Consultant*, Children's Hospital and Medical Center, University of Washington, Division of Child and Adolescent Psychiatry (Co-Investigator w/Eric Trupin, PhD & Elizabeth McCauley, PhD). *Acting Assistant Professor*, Department of Psychiatry, Division of Child and Adolescent Psychiatry, University of Washington.
1998-present	*Instructor*, Department of Epidemiology, Developed and taught *Psychosocial Epidemiology: The Application of Epidemiological Methods in Social Psychiatry*
2000-present	*Assistant Professor*, Division of Child and Adolescent Psychiatry and *Adjunct Assistant Professor*, Department of Epidemiology, University of Washington.

Academic and Professional Awards:

Gatzert Child Welfare Fellowship Award, supporting dissertation research, Fall 1997.
Outstanding Student Award, University of Washington, Department of Epidemiology, 1998.
Distinguished Paper Award, Eleventh Annual Research Conference, A System of Care for Children's Mental Health: Expanding the Research Base, University of South Florida, 1999.

Publications:

Vander Stoep A (1980). *Health in Tanzania- 1979.* Report published by the United States Agency for International Development.

Vander Stoep A, Melville EL, Bohn P (1991). Prediction of discharge against medical advice from adolescent residential treatment. *Journal of Hospital and Community Psychiatry*, 42, 725-728.

Vander Stoep A (1992). Through the cracks: Transition to adulthood for severely psychiatrically impaired youth. in *Fourth Annual Research Conference Proceedings, A System of Care for Children's Mental Health: Expanding the Research Base,* University of South Florida: 357-368.

Vander Stoep A, Blanchard T (1993). Introduction of mental health case management to homeless youth in King County, Washington. in *Fifth Annual Research Conference Proceedings, A System of Care for Children's Mental Health: Expanding the Research Base*, University of South Florida: 337-346.

Vander Stoep A, Taylor B, Holcomb L (1994). Using aggregated progress indicators to evaluate treatment foster care: Replication of a statewide study. and

Vander Stoep A, Taub J, Holcomb L (1994). Follow-up of adolescents with severe psychiatric impairment into young adulthood. in *Sixth Annual Research Conference Proceedings, A System of Care for Children's Mental Health: Expanding the Research Base*, University of South Florida: 315-320; 373-379.

Taub J, Vander Stoep A (1995). King County children's mental health evaluation: Differences by level of service intensity. in *Seventh Annual Research Conference Proceedings, A System of Care for Children's Mental Health: Expanding the Research Base* University of South Florida: 323-328.

Davis M, Vander Stoep A (1996). *The Transition to Adulthood among Adolescents Who Have Serious Emotional Disorders: At Risk for Homelessness.* Report published by the National Resource Center for Homelessness and Mental Illness, Delmar, NY.

Vander Stoep A, Evens C, Taub J (1997). Risk of juvenile justice referral among children in a public mental health system. *Journal of Mental Health Administration* 24 (4): 428-442.

Evens C, Vander Stoep (1997). Risk factors for juvenile justice system referral among children in a public mental health system. *Journal of Mental Health Administration* 24(4): 443-455.

Davis M, Vander Stoep A (1997). The transition to adulthood for youth who have serious emotional disturbance, Part I: Developmental transition and young adult outcomes. *Journal of Mental Health Administration* 24 (4): 400-427.

Vander Stoep A , Link BL (1998). Social class, ethnicity and mental illness: The importance of being more than earnest. *American Journal of Public Health* 88 (9):1396-1402.

Williams M, Vander Stoep A, Jones R (1998). Families as full research partners. *Claiming Children*, national newsletter of the Federation of Families for Children's Mental Health, Summer Issue: 6-8.

Vander Stoep A, Williams M, Jones B, Trupin E (1999). Parents as full research partners: What's in it for us? *Journal of Behavioral Health Services and Research* 26:329-344.

Vander Stoep A., Beresford S, Weiss NS (1999). A didactic device for teaching epidemiology students how to anticipate the effect of a third factor on the exposure/outcome relationship. Letter to the Editor, *American Journal of Epidemiology* 150:221.

Vander Stoep A (1999). Maintaining high subject retention in follow-up studies of adolescents with psychiatric disorders. *Journal of Child and Family Studies* 8 (3):305-318.

Vander Stoep A, Beresford S, Weiss NS, McKnight B, Cauce AM, Cohen P (2000). Community-based study of the transition to adulthood for adolescents with psychiatric disorder. *American Journal of Epidemiology* 152 (4):352-362.

Mease PJ, Goffe BF, Metz J, Vander Stoep A, Finck B, Burge DF (2000). Etanercept in the treatment of psoriatic arthritis and psoriasis. *Lancet* 356:385-390.

Vander Stoep A, Davis M (2000). Transition: A time of developmental and institutional clashes. In HB Clark and M Davis, editors, *Transition to Adulthood: A Resource for Assisting Young People with Emotional or Behavioral Difficulties*, Paul H. Brookes Publishing Co. Baltimore: 3-28.

Embry L, Vander Stoep A, Evens C, Ryan K, Pollack A (2000). Risk factors for homelessness in youth released from a psychiatric residential treatment facility. *Journal of the American Academy of Child and Adolescent Psychiatry* 39 (10): 1293-1299.

Vander Stoep A, Weiss NS, Beresford SAA, McKnight B, Cohen P (2002). Which measure of psychiatric disorder—diagnosis, number of symptoms, or adaptive functioning—best predicts adverse young adult outcomes? *Journal of Epidemiology and Community Health* 56 (1): 56-65.

Vander Stoep A, Green L, Williams M, Huffine C, Jones RA (2001). A family empowerment model of change drives the development of a children's system of care. In Hernandez M, Hodges S, Editors. *Tools, Case Studies and frameworks for Developing Outcome Accountability in Children's Mental Health*, Baltimore, MD:Paul H. Brooks publisher, pp41-59.

Vander Stoep A, Weiss NS, Saldanha E, Cheney D (in press). What proportion of failure to complete secondary school in the U.S. population is attributable to adolescent mental illness? *Journal of Behavioral Health Services and Research.*

Vander Stoep A, Williams M, Huffine C (in press). Family driven treatment: Families as full partners in the care of children with psychiatric illness. Chapter 11 in HS Ghuman, MD Weist and RM Sarles, Eds. *Providing Mental Health Services to Youth Where They Are: School-Based and Community-Based Approaches*, Brunner/Mazel publisher.

Research Support:

ACTIVE

Developing Prime Time Project for Double Jeopardy Youth
10/1/00-9/30/03
The major goals of this research are to further the development of an intervention that incorporates motivational enhancement and cognitive behavioral skills training into multisystemic therapy to reduce criminal involvement and substance use in African American juvenile offenders with co-occurring mental health and substance use disorders.

Developmental Pathways to Depression
9/1/01-8/31/02
The goal of this project is to find an accurate and efficient way to identify early in the middle school years children who are at risk of developing depression.

Emergence of Depression and Co-occurring Disruptive Behavior Problems
National Institute of Mental Health (Ann Vander Stoep, Ph.D., PI) 10/1/01-9/30/06
The goal of this project is to understand how children with depression, alone and children with depression and co-occurring disruptive behavior problems differ in antecedents, phenomenology, and outcomes.

PENDING

Middle School to High School Transition Project
7/1/02-6/30/07
This project tests the effectiveness of a school-based preventive intervention for reducing depression and substance use and increasing school success during the transition from 8th to 9th grades.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Noel S. Weiss	Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
Stanford University, Stanford, CA	AB	1965	
Stanford University, Stanford, CA	MD	1967	
Harvard School of Public Health, Boston, MA	MPH	1969	
Harvard School of Public Health, Boston, MA	DrPH	1971	Epidemiology

Positions and Honors:

Epidemiologist, Office of Health Statistics Analysis, National Center for Health Statistics, Rockville MD, July 1971 - July 1973

Head, Cancer Surveillance System, Program in Epidemiology and Biostatistics, Fred Hutchinson Cancer Research Center, Seattle WA, July 1973 - March 1975

Assistant Member, Fred Hutchinson Cancer Research Center, Seattle WA, January 1974 - June 1976

Associate Member, Fred Hutchinson Cancer Research Center, Seattle WA, July 1976 - June 1982

Member, Fred Hutchinson Cancer Research Center, Seattle WA, July 1982 - Present

Assistant Professor, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle WA, July 1973 - June 1976

Associate Professor, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle WA, July 1976 - June 1979

Professor, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle WA, July 1979 - Present

Chairman, Department of Epidemiology, School of Public Health and Community Medicine, University of Washington, Seattle WA, July 1984 - June 1993

Selected peer-reviewed publications: (From a total of 381)

Crump C, Chen C, Appelbaum FR, Kopecky KJ, Schwartz SM, Willman CL, Slovak ML, **Weiss NS**. Glutathione S-transferase theta 1 gene deletion and risk of acute myeloid leukemia. Cancer Epidemiol Biomarkers Prev. 2000;9:457-60.

Hagan H, McGough JP, Thiede H, Hopkins SG, **Weiss NS**, Alexander ER. Volunteer bias in nonrandomized evaluations of the efficacy of needle-exchange programs. J Urban Health 2000;77:103-12.

Flood DM, **Weiss NS**, Cook LS, Emerson JC, Schwartz SM, Potter JD. Colorectal cancer incidence in Asian migrants to the United States and their descendants. Cancer Causes Control 2000;11:403-11.

Cummings P, McKnight B, **Weiss NS**. Modeling the effects of age at and time since delivery on subsequent risk of cancer. Epidemiology 2000;11:479-81.

Li CI, **Weiss NS**, Stanford JL, Daling JR. Hormone replacement therapy in relation to risk of lobular and ductal breast carcinoma in middle-aged women. Cancer 2000;88:2570-7.

Vander Stoep A, Beresford SAA, **Weiss NS**, McKnight B, Cauce AM, Cohen P. Community-based study of the transition to adulthood for adolescents with psychiatric disorder. Am J Epidemiol 2000;152:352-62.

Sanderson M, Williams MA, **Weiss NS**, Hendrix NW, Chauhan SP. Oral contraceptives and epithelial ovarian cancer. Does dose matter? J Reprod Med 2000;45:720-6.

Stehman-Breen CO, Sherrard DJ, Alem AM, Gillen DL, Heckbert SR, Wong CS, Ball A, **Weiss NS**. Risk factors for hip fracture among patients with end-stage renal disease. Kidney Int 2000;58:2200-5.

Holt VL, **Weiss NS**. Recommendations for the design of epidemiologic studies of endometriosis. Epidemiology 2000;11:654-9.

Hill DA, **Weiss NS**, Beresford SAA, Voigt LF, Daling JR, Stanford JL, Self S. Continuous combined hormone replacement therapy and risk of endometrial cancer. Am J Obstet Gynecol 2000;183:1456-61.

Hagan H, Thiede H, Weiss NS, Hopkins SG, Duchin JS, Alexander ER. Sharing of drug preparation equipment as a risk factor for hepatitis C virus incidence. AmJ Public Health 2001;9:23-27.

Buist DSM, LaCroix AZ, Barlow WE, White E, **Weiss NS**. Bone mineral density and breast cancer in postmenopausal women. J Clin Epidemiol 2001;54:417-42.

O'Meara ES, Rossing MA, Daling JR, Elmore JG, Barlow WE, **Weiss NS**. Hormone replacement therapy after a diagnosis of breast cancer in relation to recurrence and mortality. J Natl Cancer Inst 2001;93:754-62.

Buist DSM, LaCroix AZ, Barlow WE, White E, Cauley JA, Bauer DC, **Weiss NS**. Bone mineral density and endogenous hormones and risk of postmenopausal breast cancer. Cancer Causes Control 2001;12:213-22.

Weiss NS, Rossing MA. Non-hormonal contraception and the risk of ovarian cancer. Epidemiology 2001;12:300.

Weiss NS. Policy emanating from epidemiologic data: What is the proper forum? Epidemiology 2001;12:373-4.

Li CI, Malone KE, Weiss NS, Daling JR. Tamoxifen therapy for primary breast cancer and risk of contralateral breast cancer. J Natl Cancer Inst 2001;93:1008-13.

Cook LS, **Weiss NS**, Pharris-Ciurej N, Schwartz SM, White E. Colorectal cancer following tamoxifen therapy for breast cancer (United States). Cancer Causes Control 2001;12:404-10.

Weiss NS, Rossing MR. Oestrogen-replacement therapy and risk of ovarian cancer. Lancet 2001;358:438.

Reed SD, Weiss NS, Srouji SS. Combined post-menopausal hormone therapy and risk of endometrial cancer. Menopausal Med 2001;9:7-12.

Heckbert SR, Kaplan RC, **Weiss NS**, Psaty BM, Lin D, Furberg CD, Starr JR, Anderson GD, LaCroix AZ. Risk of recurrent coronary events in relation to use and recent initiation of postmenopausal hormone therapy. Arch Intern Med 2001:161:1709-13.

Littman AJ. Voigt LF, Beresford SAA, **Weiss NS**. Recreational physical activity and endometrial cancer risk. Am J Epidemiol 2001;154:924-33.

Watson RS, Cummings P, Quan L, Bratton S, **Weiss NS**. Cervical spine injuries among submersion victims. J Trauma 2001;51:658-62.

Weiss NS. Can the "specificity" of an association be rehabilitated as a basis for supporting a causal hypothesis? Epidemiology 2002;13:6-8.

Seliger SL, **Weiss NS**, Gillen DL, Kestenbaum B, Ball A, Sherrard DJ, Stehman-Breen CO. HMG-CoA reductase inhibitors are associated with reduced mortality in ESRD patients. Kidney International 2002;61:297-304.

Vander Stoep A, **Weiss NS**, McKnight B, Beresford SAA, Cohen P. Which measure of adolescent psychiatric disorder – diagnosis, number of symptoms, or adaptive functioning – best predicts adverse young adult outcomes? J Epidemiol Community Health 2002;56:56-65.

Olson SH, Voigt LF, Begg CB, **Weiss NS**. Reporting participation in case-control studies. Epidemiology 2002;13:123-126.

Corley DA, Levin TR, Habel LA, **Weiss NS**, Buffler PA. Surveillance and survival in Barrett's adenocarcinomas: a population-based study. Gastroenterology 2002;122:633-640.

Dublin S, Rossing MA, Heckbert SR, Goff BA, **Weiss NS**. Risk of epithelial ovarian cancer in relation to use of antidepressants, benzodiazepines, and other centrally acting medications. Cancer Causes and Control 2002;13:35-45.

Chen C-L, **Weiss NS**, Newcomb P, Barlow W, White E. Hormone replacement therapy in relation to breast cancer. JAMA 2002;287:734-741.

C. Research Support.

1) NIH/NCI R01 CA 75977 (Weiss) 03/01/98 - 12/31/01 (NCE to 12/31/02)
Endometrial Cancer and Postmenopausal Hormone Therapy

This population-based case-control study will investigate the role of hormonal medications (particularly estrogen/progestin regimens) on endometrial cancer risk.

2) NIH/NCI R03 CA 80636 (Chen) 09/30/98 - 08/31/00 (NCE to 10/31/01)
Endometrial Cancer and CYP1A1, GSTM1 & T1 Polymorphisms

This is an ancillary study to a case-control study of endometrial cancer (R01 CA 75977). Blood samples will be collected and analyzed for polymorphisms in certain genes, to assess any increased risk for endometrial cancer.

3) NIH/NCI R03 CA 84540 (Weiss) 09/29/99 - 08/31/01 (NCE to 8/31/02)
Cervical Cancer Screening Efficacy in Older Women

Screening for cervical cancer, by means of the Pap smear, has demonstrably reduced the burden of cervical cancer among women of reproductive ages. However, the usefulness of screening in older women is uncertain. Using a case-control study design, this project will evaluate the efficacy of cervical cancer screening in older women (55-79 years of age), enrolled at one of two, large, health maintenance organizations in the northwestern US.

4) NIH/NCI R01 CA 64158 (Williams) 03/01/97 - 02/28/99
Diuretics and Renal Cell Cancer

This project is investigating the hypothesis that antihypertensive therapy, particularly use of diuretics, increases the risk of renal cell cancer.

5) NIH/NCI 1 R03 CA92767-01 07/31/01 - 06/30/03
Interval for Colon Cancer Screening by Sigmoidoscopy

This study will provide a rational basis to address the question of appropriate screening interval for colorectal cancer (CRC) by sigmoidoscopy. Such information will allow for the reduction in CRC incidence and mortality, while minimizing the costs associated with a sigmoidoscopy screening program.

6) NIH/NCI 1 R03 CA92706-01 07/01/01 - 06/30/03
The Androgen pathway and genetic risk of prostate cancer

The specific aim of this project is to evaluate the risk of prostate cancer associated with variant alleles of genes in the androgen pathway, including SRD5A2, AR, and PSA, among male participants in the Cardiovascular Health Study.

7) NIH/NCI P50 CA 83636 09/30/99 - 09/29/04
Pacific Ovarian Cancer Research Consortium

The Pacific Ovarian Cancer Research Consortium (POCRC) is a consortium of five non-profit organizations led by the Fred Hutchinson Cancer Research Center (FHCRC), including the University of Washington (UW), Swedish Medical Center (SMC), Pacific Northwest Research Institute (PNRI), and Cedars Sinai Medical Center (CSMC). POCRC consists of a group of scientists from a variety of disciplines who have come together to address selected issues related to the control of ovarian cancer.

8) NIH/NCI R01 CA85064 (Weiss) 07/14/00 - 12/31/02
IGF-I Levels, IGF-I Genotype, and Prostate Cancer

This nested case-control study, among male enrollees of the Cardiovascular Health Study (CHS), will investigate the role of the insulin-like growth factor-1 (IGF-I) in the etiology of prostate cancer.

9) NIH N01-WH-2-2110 (Prentice) 09/30/92 - 09/29/07
Clinical Coordinating Center for the Clinical Trial and Observation of the Women's Health Initiative

The major goal of this project is to establish and operate a Clinical Coordinating Center to support the Women's Health Initiative Clinical Trial and Observational Study. The clinical outcomes of interest include: coronary artery disease, stroke, venous thrombo-embolic diseases, breast and colorectal cancers, fractures, diabetes, and total mortality.

10) NIH/NCI R01 CA 78812 (Chen) 04/01/99 - 03/31/02
Endogenous Sex Hormones, Genetics, and Prostate Cancer

This project proposes to analyze hormone levels and genetic determinants of enzymes and assess their relationship to prostate cancer. This will be a case-control study nested within the Carotene and Retinol Efficacy Trial (CARET).

11) NIH/NCI R01 CA 85914 (Schwartz) 06/01/00 - 05/31/05
Molecular Epidemiology of Testicular Carcinoma

This population-based, case-control study will test the hypothesis that inherited variation in genes involved in stimulating testicular steroidogenesis, synthesizing and metabolizing testosterone, and androgen signaling, is related to the risk of developing of testicular germ cell carcinoma.

13) NIH/NHLBI NIH K30 HL04136 09/30/00 - 08/31/05
UW Clinical Research Training Program

This training program fosters the training of post-doctoral fellows in all of the schools of the Health Sciences Center at the University of Washington. There are both degree and non-degree programs aimed at the training of clinical investigators.

14) Dept. of Veterans Affairs N/A (Boyko) 04/01/98 - 03/31/02
Epidemiology Research and Information Center (ERIC)

This research center, funded by the Department of Veterans Affairs, supports epidemiologic research in health topics of interest to the veteran population.

15) ACS N/A (Weiss) 01/01/98 - 12/31/00
PSA Screening and Mortality from Prostate Cancer

This project seeks to estimate the impact of PSA screening on mortality from prostate cancer.

16) NIH/NCI CA 87538-01A1 (Rossing) 04/01/02 - 03/31/07
Epidemiology of Ovarian Cancer: New Hypotheses

This study addresses the hypothesis that progesterone reduces risk of epithelial ovarian cancer. The relation of exogenous progestins administered as a component of hormone replacement therapy (HRT) with disease risk will be examined, with further assessment of whether sunlight and dietary sources of vitamin D influence risk. In-person interviews will be conducted among cases and controls, and blood samples collected.

RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

The UNIM Laboratory in Kisumu: UNIM Project Male Reproductive Health Laboratory facility where this project will be done is a research standard laboratory equipped with current state of the art equipment to meet the demands of a project of this magnitude. There is a Class II safety cabinet and ability to handle all classes of microorganism except Hazard Group IV, none of which are going to be dealt with in this study. Other equipment include a refrigerated centrifuge, double water jacketed CO2 incubator, a –700Cand –200C and a number of regular refrigerators. The cryogenic facilities include a good source of dry ice supply and liquid nitrogen; we have liquid nitrogen dewars and locator tanks. As for workload, the laboratory currently has two trained technologists besides the chief technologist. Incase of increased workload, it would not be difficult to get another technologist who will undergo an in-house capacity building training to make him/her fit into the groove. Our sister laboratory in Nairobi (Department of Medical Microbiology, University of Nairobi) has facilities for flowcytometry and PCR as well as those for conventional testing.

Clinical:

Interviews, medical exams, specimen collection and HIV test : We plan to rent rooms in health facilities at the two study divisions: Maranda in Bondo District and Boro in Siaya District. Female clinical officers with training and experience on how to collect and store specimens in a field setting and also on how to manage STD syndromically following the standard of care algorithm in Kenya will be hired and stationed at these centers. Field site for all data collection activities will be the existing district hospitals which have adequate space to house the project activities (Bondo and Siaya District Hospitals). In addition, the facilities have electricity which we will use for our refrigerators for temporary storage of specimens. We shall provide the equipment and supplies for taking various specimens (vacutainer tubes and needles, sterile swabs, specimen transport tubes, urine containers, cool boxes, gloves, etc). Experienced female nurse-counselors, also trained in VCT by CDC and in carrying out interviews, will also be stationed at the sites. They will perform parallel HIV tests using Unigold and Determine test kits. Finger prick method will be used to obtain blood. In case of discordant results, they will draw 5m/s of venous blood for ELISA test and store it at room temperature until it is taken to Kisumu at the end of the day.

Animal:

Computer:

There are two PCs and one laptop computer on hire at minimal cost at the Impact-Research and Development Consultancy

Office:

Impact-Research and Development Consultancy will avail 3 rooms for rental: for data entry, study records, and administration.

Other:

a. Long-term Goal and Specific Aims of the Study

We propose to do a systematic scientific investigation into the possible association between the phenomenon of widow inheritance (WI) and the incidence of HIV among the Luo ethnic community in Nyanza Province, Kenya. Many reports [3,4,9,23-25, see also Newspaper Reports expressing public opinion on the same: 6,15,26-29] have isolated the phenomenon of WI to be a key factor in explaining the alarming HIV prevalence among the Luo population. The focus of this proposed study is to use the Luo case as a representative of the widows and women across many cultures in Sub-Saharan Africa in particular and others elsewhere in general that still practice WI. Some intervention approaches have registered varying degrees of success in this region, e.g. in Uganda and Senegal [30-35], but more scientific knowledge is still needed to support further intervention and to develop new paradigms that can be effective in combating the HIV/AIDS scourge [8]. This is more so given that over 90% of HIV infections in African adults arise form heterosexual intercourse [1]. Interventions based on sexual behavior in Africa therefore constitutes the centerpiece in the fight against HIV/AIDS [36-47]. In Africa, many sex related issues have a solidified cultural sub-structure so that behavior thereof revolves around intricate and highly complex cultural prescriptions. Many of the HIV/AIDS intervention programs addressing WI in Africa and Kenya more specifically have been built on the practice as an observable cultural superstructure in complete ignorance of the compelling under-current of factors that shape up this custom (see also 48-52]. Among the Luos for example, WI is a cultural practice that has very subtle cultural underpinning and which therefore thrives on a delicate labyrinth of sexual detail. As Agot [8] argues, the fact that many HIV/AIDS intervention players have designed their programmes around this manifest cultural superstructure could explain the dismal performance so far registered in their efforts. They are assuming that the inherited widows are more exposed to the risk of HIV infection than the uninherited widows, yet none of these studies has undertaken any empirical inquiry into this postulated relationship. To our knowledge, this proposed study will be the first scientific investigation into the possible association between WI and HIV incidence and therefore holds the first real possibility of assessing WI as a potentially effective HIV intervention tool. If the practice, or its specific components, is found to have an association with HIV incidence, it could have a far-reaching impact in controlling HIV/AIDS epidemic among the most vulnerable population in Sub-Saharan Africa and elsewhere in the world where WI still exists as a cultural practice.

Briefly therefore, the specific aims of the study are as follows:

Aim 1: Assess the association between widow inheritance and acquisition of HIV in Nyanza Province, Kenya.

Aim 2: Examine the relationship between the two types of inheritors (by brothers-in-law versus by professionals) and HIV infection

Aim 3: Evaluate the difference in HIV risk associated with the different purposes of inheritance (for companionship and support versus for sexual cleansing)

Aim 4: Identify correlates of inheritance overall, as well as of the different types and purposes of the practice.

b. 1.0: Background and Significance

The latest UNAIDS report estimated that by December 2001, 40 million people were living with HIV/AIDS worldwide, 28.1 million (70.3%) of whom were in sub-Saharan Africa. The subcontinent was also leading in the number of new infections (68%), HIV-related deaths (80%), AIDS orphans (91.7%), and infected women (81.9%) [1]. Over 90% of HIV infections in African adults are reported to result from heterosexual intercourse. In the absence of a vaccine, behavioral interventions still hold the key to addressing the scourge. In light of this, the main HIV prevention strategies promoted by many countries in the region include HIV testing and counseling, increased condom use, reduction in numbers of sexual partners, and treatment of sexually transmitted infections. Yet after many years of such behavioral interventions, the impact has been minimal as HIV continues to spread rapidly in many parts of the continent, notably Southern Africa [1]. In Kenya, the seroprevalence has plateaued in the last 2 years, even though at a high level of 14% in the general population [1,2]. However, there are marked variations within the country and among different sub-populations. Of the 43 ethnic communities, the Luo of Nyanza Province recorded the highest HIV prevalence (29.8%) in 2001. This community accounts for 12% of the national population [2-4].

The Luo community represents a paradox in the HIV/AIDS epidemic. On the one hand, it has accounted for the highest prevalence of the disease in the country since the late 1980s when complete data became available [2]. On the other hand, it is the most researched group in terms of identifying risk factors for HIV [3,5-9]. It is also the highest recipient of some of the most intense interventions in the country to date [5,7-9]. The result of this is a 99% HIV awareness rate in the community against a background of almost 30% seroprevalence. Such discordant findings call to question the effectiveness of the current interventions in the community.

One of the explanations offered by the government for the disproportionate prevalence of HIV in Luo Nyanza is the societal beliefs, practices, and norms promoting sexual networking, especially widow inheritance (WI). WI is a practice where a widow is 'taken over' by a brother or a cousin to the late husband and where, even though the relationship does not constitute a formal marriage, sex is often an integral part [8,10-16]. The practice of WI has been reported in many parts of the developing world, especially in Sub-Saharan Africa [14]. The practice is particularly strong in Kenya (8,10,11,15], Uganda, Mali Burkina Faso, Sierra Leone, Botswana, Zambia and Zimbabwe [14,17], Rwanda [18], Ghana [19,20], and Namibia [14]. It is characteristic of patrilineal and patrilocal societies among whom the widow, as well as her children and all the property, belong to the husband and when he dies, to his family [8,11,14,21].

Studies conducted among the Luo of Kenya found that between 51-57% of the widows got inherited within a year of widowhood [8,10,11]. Besides the 51% (n=91) of the widows who had been inherited within a year of widowhood reported by Okeyo and Allen [10], 36% additional ones were planning to be inherited and only 12% refused to be inherited due to fear of contracting HIV through the inheritors. The authors also found that one third of the 51% already inherited had 'divorced' previous partners, and there were also cases where the current inheritor was the third since the death of the spouse, in just one year. In addition, 32% of the inheritors had a history of previously inheriting other widows, and only 2.2% of the widows reported ever using condoms since the death of their spouses. Agot's 1996 study [11] found that 85% of the widows took the initiative in arranging to be inherited, most of them citing keeping traditions and 'protecting' their families from misfortunes as their reasons for doing so, and that 71.2% of the 216 parents interviewed wished to see the tradition upheld. In the 1999/2000 study by Agot [8], it was reported that respondents viewed inheriting widows as a check against the rapid spread of HIV whereas the government viewed it as a risk factor even though there have not been scientific evidence to support the relationship. The contrasting conceptualizations of the association between HIV and widow inheritance between the government and the practitioners had resulted in ineffective interventions being designed to address the practice.

Among the Luo community, inheritance is done to discourage widows from abandoning their matrimonial homes and their children, to guard against having sexual relations outside the husband's clan, to enable them to have children to continue the lineage of their husbands (hence the requirement that an inheritor should be the husband's brother or cousin), and to enable them fulfill certain customary rites for which sex is mandatory, such as to mark the start of farming seasons (cultivating, planting, weeding, and harvesting), to put up a home or to mark the birth, burial or marriage of a loved one [8,10,11,13]. The practice is thus perceived as a requisite for biological and social reproduction of self and of the survival of the community in terms of food, shelter, birth, marriage, and death. As such, a widow's family and the society as a whole are directly dependent on her participation in the custom. Often, even when the decision to be inherited may appear voluntary, the widow is most likely responding to forces outside her realm of free decision, and many times increasing risk to self becomes less threatening than the survival of her immediate and extended family [8,10,11].

How would WI constitute risk for HIV?

The practice of widow inheritance has the potential to both check and enhance the spread of HIV. In a study on WI carried out among the Luo in 1999/2000 [8], respondents argued that a widow who is not inherited may be more inclined to be involved with more than one sexual partner and, if seropositive, would pose a greater danger to the community by transmitting HIV to an unknown number of people (scenario 1). And if she is negative for HIV, she would also be at a greater risk for acquiring HIV if she were uninherited than if she were inherited. This is because inherited, she would only infect one man 'at a time' (scenario 2) if she is seropositive. And if she is seronegative, having one sexual partner—the inheritor—would reduce her chances of acquiring HIV relative to a widow who is uninherited and who is therefore likely to have multiple partners. Scenario 2 represents a closed system (of the inheritor, his wife, and the widow) in which the virus would probably be contained among three people for an average of 8-10 years (incubation period of HIV in Kenya [3]). The turnover of men in Scenario 1, however, has the potential to be much higher, much faster, and to result in a more far-reaching spread of HIV in the community compared with Scenario 2. Hence, to many people of the Luo community, it logicical to argue for inheritance as a way of reducing the risk of acquiring HIV by the widow, and also for checking the rapid spread of the virus in the community at large.

On the other hand, widow inheritance can enhance the spread of HIV. Traditionally amongst the Luo, a widow was supposed to be inherited by a brother or a cousin to her late husband. The contract was permanent and binding [8,10,11,13,22]. However, the practice has gone through changes, some of which have potentially increased the vulnerability of widows to HIV. For example, fear of contracting HIV, working outside the rural homes, religious affiliation, and enlightenment acquired through education have, in a variety of ways, made in-laws less inclined to partake of WI. As a result, many widows have had to turn to 'professional inheritors'—a crop of men who typically move from one widow to another, many times keeping several widows concurrently [8,10,11]. Often, inheritance by professionals is done to observe sexual rituals such as widow cleansing, and are hence casual. Once the event is over, the contract is severed until another need arises for sexual ritual to be observed. Widows engaging in this style of inheritance often end up with different inheritors each time. Inheritance contracted by professional inheritors and for purposes of partaking of a sexual rite would not allow adequate background check on the "couple's" past sexual behavior. At the same time, it would not provide a conducive environment for either the widow or the inheritor to request HIV testing prior to sex. With this in mind, it is suggested that the inheritance style practiced by the Luo today might increase vulnerability of the widows, and community at large, to HIV infection.

To recap, WI as practiced by the Luo today has non-uniform implications for HIV infection. One, the practice can be viewed as having a double purpose: for companionship and support vis-à-vis to enable the widow to partake of the activities where ritual sex is required. The latter purpose would pose a higher risk

for HIV than the former. And two, WI is slowly shifting from the domain of the brothers-in-law to professional inheritors. Here also, the second type of inheritance would pose a higher risk for HIV infection than the first. Given the varying types and purposes of WI, as well as the two views of the practice, namely, as a check against, and as a conduit for, HIV transmission, it is important to establish the risk posed by the practice because massive resources in intervention are already being devoted to programs geared toward eliminating the practice of WI as an HIV/AIDS control measure. Such interventions have hitherto not benefited from being informed by a systematic empirical investigation into this association [8,10,11]. It is possible these resources are being misplaced, casting doubts into the efficiency with which African countries use donor funds and scanty local resources in research–led HIV/AIDS intervention. The study hopes to rise above the said speculative assertion about this association. It is also overdue, since it will provide data that would serve as a source of teaching materials to empower the Ministry of Health, local opinion leaders, cultural brokers, church leaders, village headmen etc in the fight against HIV/AIDS.

b. 1.1: Theoretical/Conceptual framework:

The concept of 'spaces of vulnerability' will serve as the theoretical framework informing the proposed study. Watts and Bohle [53] and Delor and Hubert [54] present vulnerability as a multilayered and multidimensional social space defined by the prevailing political, economic and institutional capabilities of people to secure basic needs in specific places at specific times. 'Spaces of vulnerability' is conceptualized as an *intersection* of three characteristics: the risk of *exposure* to a crisis situation, the risk of inadequate *capacities* or resources to cope with these situations, and the potential risk of being subjected to *severe consequences* as a result of being exposed to the crises. Thus, the most vulnerable individuals, groups, and classes, for example, are those most exposed to perturbations, who possess the most limited coping capability, who suffer the most from the impact of the crisis, and who are endowed with the most circumscribed capacity for recovery [53, see also 55-60]. In this respect, the type and magnitude of vulnerability is defined by, and subject to, an interaction between and among the three characteristics and their various components. For instance, a combination of several exposure conditions would increase the risk of the exposed individual to the crisis of interest than a single exposure. Likewise, a combination of inadequacies to cope, such as lack of resources, capacity and opportunity to cope, would result in a more serious inability to address a given crisis. In terms of HIV and widow inheritance generally, vulnerability can be viewed as the extent to which the widows are capable of making and effecting free and informed decisions about their lives [8]. It is an analysis that recognizes how broader contextual issues such as societal gender relations, personal characteristics of the widow, religious beliefs, societal obligations, and so on, influence decision-making behavior, as well as the subsequent capacity to reduce personal vulnerability that may arise from these decisions (or lack thereof).

In terms of widow inheritance among the Luo specifically, Agot [8] discussed three sets of conditions that would predispose a widow to inheritance, particularly for purposes of sexual cleansing and/or by a professional inheritor. These included: i) Religious affiliation (some faiths denounce the practice while for others, it is part of the doctrinal teachings and is encouraged, even mandated). ii) Personal background characteristics (level of education and income, occupation, and residence—i.e., whether the widow is living on the same compound with in-laws or in her own home. The latter would give her a measure of autonomy in decision-making). iii) Social responsibility (the widow has a responsibility to be inherited for purposes of sexual cleansing so that her immediate and extended family do not encounter misfortunes. For instance, she would be particularly vulnerable if she is a mother, a mother-in-law, a daughter, a daughter-in-law, or a co-wife, each of which places specific demands on her to observe the tradition). Intersections/overlapping of different aspects of these conditions (e.g., a widow who is of a faith that requires inheritance, who lacks resources to delink from the influence of her in-laws, and who, as a mother, is under pressure from her children to be inherited so that they do not suffer misfortunes) determine the magnitude of vulnerability. The 'environment' created by such intersections of predisposing factors is what is referred to as 'spaces of vulnerability' to HIV infection through WI [see

also 61-67]. In this study, we postulate that the intersection of these factors in the life of a widow will determine whether or not she will be inherited, for what purpose (for companionship/social support or sexual cleansing) and by which type (by a brother-in-law or a professional inheritor). Identifying these predictors, and the magnitude and direction of risk posed by their various combinations, will provide critical information for policy makers to design interventions that not only address the risky components of the practice of WI, but also those that address the underlying factors that predispose widows to partake of the risky type of this tradition.

b. 1.2: Assumptions

i) WI and its possible association with HIV incidence can only be understood in terms of the various categories (types and purpose) of the phenomenon and its correlates (widow's background characteristics) and not only by looking at it as one indivisible cultural superstructure.

ii) Once we identify the components of WI that work in concert with HIV infection to impact negatively on the health of Luo women, we can then usefully tackle the epidemic through research–informed interventions.

iii) If cultures which practice WI get correct information about this association (in whatever direction), they will review accordingly their position regarding the same and this will be a better approach in the fight against HIV/AIDS than the hitherto scientifically uninformed interventions that have been going on for the past 15 or so years.

b. 1.3: Potential scientific contribution

One main shortcoming of the studies that have been conducted so far on WI vis-à-vis HIV infection is that none of them has systematically investigated the association between WI and HIV incidence [8]. Because all the studies that have suggested a relationship between these two variables have never undertaken any truly controlled study, their postulation of such an association is still empirically wanting.

Given such research status on WI, we believe that the concentration of interventions that have hitherto used the possible eradication of WI as a focus of HIV/AIDS control and prevention among the Luo community might still be mis/uninformed and might result in dissipating scanty resources in untested ventures [8]. A scientifically controlled study like this proposed one is therefore still needed as an intervention imperative. Further to a simple association between WI and HIV infection, this proposed study will go ahead to 'dissect' the phenomenon of WI and investigate the components of it that might be more risky for HIV acquisition than others. Addressing these components rather than advocating for a complete overhaul of the whole institution of inheritance may be a more useful approach to change such culturally embedded practice. In fact, it may not even be the risky components that would need to be addressed; it could be the factors predisposing widows to partake of those risky components that might need intervention. One of the goals of this study is to identify the predictors (correlates) of the risky components of WI.

This proposed study will address these gaps by attempting the first scientific study of this postulated association to find out which aspects of WI need what type of intervention and policy so that resultant programs can be tailor-made to answer to the specifics of the risk factors within WI as an observable cultural superstructure. It is an argument in favor of a micro-intervention approach in fighting HIV. If WI as a whole or aspects of it are found to be significantly associated with HIV incidence, it would be possible to develop and expand the frontiers of HIV intervention tools at policy, planning and program levels and this would have a far reaching impact not just among women or the Luos, but in sub-Saharan Africa and beyond where WI as a valued cultural practice is still deeply rooted and where HIV prevalence rates continue to soar above 10% in the general population.

Overall therefore and to recap, this proposed study will inform policy makers on the actual risk of WI for HIV acquisition and will also help us to debunk the concept of WI and quantify the magnitude of risk associated with each component. Many African cultures have been blamed wholesale as risk behaviors for HIV infection [see, for example, 38,39,48,50,52,58,60]. The study will shed scientific light on this practice as an example of the ones currently being blamed. It will allow us to examine factors that predispose widows to being inherited, and perhaps as Agot [8] argues, it is only certain components of WI that may pose HIV risk for the widow. Agot's dissertation was based on qualitative examination of the potential risk of the practice on widows. The proposed study takes this a step further to quantify the risk posed by the practice.

c: Preliminary Studies

Because the Principal Investigator will provide hands-on coordination in the field on an on-going basis, and also because the proposed study is further research designed to pick up from her recent study on WI in the same population, it is more appropriate to describe her preliminary studies that led to this proposal. For her PhD dissertation in Medical Geography, entitled: Widow inheritance and HIV/AIDS interventions in Sub-Saharan Africa: Contrasting conceptualizations of 'risk' and 'spaces of vulnerability'", the PI carried out an ethnographic study among the Luo ethnic community in Kenya between 1999 and 2000 to explore why intervention programs have had little success in changing the attitudes and behavior of the community towards the practice of widow inheritance. Primary data was obtained from 66 focus group discussions, 161 open discussions, and 11 key informant interviews, altogether covering close to 12,000 men and women across all the Luo districts of Nyanza Province. She found that the main reason for the dismal impact of the programs is that the providers and the recipients of the interventions are defining the 'risk' associated with the practice differently. To providers, widow inheritance is a risk behavior for HIV acquisition and transmission and should be discarded, while to the recipients, the practice is protective against the spread of the virus and should be revamped. She recommended an epidemiological study to ascertain whether widows who are inherited are at a higher risk for HIV infection compared to those who remain uninherited. The proposed study is thus a response to this recommendation. During this study, she reported that many of the women, including widows, were open to knowing their serostatus. Also, the PI carried out a study in 1995-96 on the origins and meanings of a number of cultural practices among the Luo community, including widow inheritance, polygyny and rites of passage. In addition, she is also the founder of a Community Based Organization in Bondo District, Ushindi Children's Support Services, whose portfolio includes organizing health talks for widows' groups in Barchando sub-location in Bondo District.

Besides the two studies directly dealing with WI among the Luo, the PI has also carried out a study on male circumcision in the same community. Like widow inheritance, the absence of male circumcision is a major cultural identity of the community and one that is very sensitively guarded. By discussing with people their perceptions about the practice and its potential relationship with HIV/AIDS and screening 811 circumcised and uncircumcised men (this is a requirement in some religious denominations) for HIV, she was able to grapple with issues touching on culture, sexuality, and religion. Currently, the PI is working in another circumcision study in Kisumu where her role includes coordinating the research activities and reaching out to the Luo community to support and participate in the study.

Prior to the two studies, the PI had also carried out two other smaller studies in the same community that are relevant to this application. In one, she conducted a Knowledge-Attitude-Practice (KAP) study of the potential risks of widow inheritance and polygamy for HIV (HIV tests were not done), and in another, she investigated gender responsibilities and women's decision-making behavior in family planning choices. Of additional benefit to the study is that she a Luo and native of Nyanza Province where the project is proposed. As such, and also because of her prior research experience, she has complete familiarity with

the study site, the local language, the social organization and events, including the culture of widow inheritance.

Mr Obare, the co-investigator, worked with the PI in both her widow inheritance and circumcision studies as an interviewer, community mobilizer, and focus group facilitator. In addition, he is also a social scientist and a Luo who understands the cultures very well. He will be the Project Coordinator of the proposed study.

d 1.0: Research Design and Methods

We are proposing a prospective cohort study of the association between widow inheritance and HIV infection among the Luo ethnic community in Nyanza Province, Kenya. Participants will be recruited from widows' groups, rosters of deaths obtained from the Assistant Chiefs who issue burial permits (the Assistant Chiefs will identify from the roster of deceased men whose widows are living in the neighborhood), by announcements at weekly Chiefs' meetings (*baraza*), in churches, and in women's groups. We shall also put posters in market places, bus stops, at the entrances to public and private health facilities, and at communal domestic water sources frequented by women. In addition, we will identify other sources of potential clients from Focus Group Discussions (FGDs) with widows prior to recruitment. FGDs will be organized and run in every division to bring together widows (individuals, groups, etc) at the preliminary stage of the study to explore into and find direction on many study aspects. Particularly, the approach will help us to involve the study population in designing better ways of getting more participants, location of field sites in view of obvious logistics of transport, fare refunds, and other salient issues like participant retention and so on (details in Appendix 1).

The study participants will be recruited from among widows aged 18-49 years who are residents of the study districts and plan to remain there for the 2 years during follow-up. Most inherited Luo widows were reported to be under the age of 50 years [8]. They will undergo counseling and HIV testing and those who are seronegative for HIV will be requested to consider joining the study. At this visit, the protocol and procedures of the study will be explained to them briefly, after which they will be given a copy of the consent form to take home to study and consult with family and friends if needed. If they agree, they will be given an appointment to return for enrolment within one week of the screening visit. Female nurse-counselors who are *Dholuo*-speakers will handle this session. At the enrolment visit, the client will go over the consent form with the counselor, and if she consents to join the study, blood will be drawn, urine specimen and swabs will be collected, a medical history will be taken, and they will be given a medical exam. All consenting participants will be interviewed to obtain socio-demographic and health information and to assess behavioral risk factors. Participants will be given HIV testing and counseling one and three months after enrolment and again at three-monthly intervals for a total of 24 months (at 1,3,6,9,12,15,18,21, and 24 months). The 3-mothly intervals are recommended to capture the frequent changes anticipated in inheritance status. For instance, the incidence of inheritance is expected to rise with growing seasons (during cultivation in Dec-Feb, planting in Feb/Mar and Sept, weeding Apr/May and Nov, and harvesting in Jul/Aug and December.) because for many widows, these seasons are ushered in by ritual sex. At these visits, clients will also undergo medical exams, be interviewed on sexual behavior and medical history since the previous visit, and be asked to give specimens (blood, urine and swabs) for STD testing. Treatment and/or referral will be given to those who require it. In addition, clients may come to the study center for unscheduled visits at any time during the 24 months of follow-up when they are part of the study. Unscheduled visits are anticipated to be the interim visits made when counseling or medical attention is required.

Clients will be counseled at enrolment and all follow-up visits to reduce their risk for HIV infection by consistent condom use and, where applicable, reductions in numbers of sex partners. Counseling on condom use and sexual risk reduction will be provided by trained, experienced, *Dholuo*-speaking female nurse-counselors. A *Dholuo*-speaking female Clinical Officer will perform medical exams, provide

treatment, and interview on medical history. The main outcome will be HIV incidence while secondary outcomes include incidence of STIs (Gonorrhea, Chlamydia Trachomatis, Chancroid, Syphilis, and Trachomona Vaginalis).

d 1.1: Measuring exposure

Exposure is inheritance and will be divided into: i) type of inheritance (either by an in-law, i.e., brother or cousin to the husband, or by other non-relative to the husband, i.e., professional inheritors) and ii) purpose of inheritance (for companionship/support or to observe sexual cleansing). At enrolment, the inheritance status of consenting eligible widow will be recorded and treated as time zero. Follow-up visits will be scheduled at 1 and 3 months at the beginning, and every three months subsequently during which time clients will be asked if there has been a change of status since the previous visit and if so, when it occurred. In addition, the clients will be given diaries in which to keep record of sexual activity (To be prepared after discussions with widows during Focus Group Discussions). For those who are illiterate, we will depend on their memory and ability to report correctly on sexual activity in the previous 3 months, and to categorize their responses into: always/all the time, most of the time, half of the time, rarely/few of the times, never, don't know, refused to answer. In addition, they will be given printed symbols which they will transfer from one envelop to another when they have sex with and without a condom (e.g., green beads for condoms and red for no condoms). They will go through the process with the nurse-counselor at enrolment visit. The purpose of this is to ascertain, in as much as possible, when exposure status changes. (This will be tried out for 2 months initially to assess if reliable information is being captured.)

d 1.2: Determination of exposure person–time (person-years):

i. Widows who have become inherited since the previous visit will describe the type of inheritor and their reasons for inheritance. The period between the time of the previous visit and when the widow got inherited will contribute to the unexposed person–years while the period between the onset of inheritance and the current visit contributes to the exposed person–years for the respective type and purpose of inheritance.

ii. For widows who were inherited at the previous visits and have remained in the same relationship, the entire period will contribute to the exposed person-years for the respective type and purpose of inheritance.

iii. Widows who were inherited at the previous visit and are still inherited but have changed the type and/or the purpose for inheritance: the period between the time of the previous visit and when the status changed e.g. from being inherited by a brother in-law to being inherited by a professional inheritor, will contribute to the exposed person-years for inheritance by the brother-in-law while the period from the change over time to the current visit will contribute to exposed person–years for inheritance by professional inheritors.

iv. For widows who were not inherited and have remained so since the previous visit, the entire period since the previous visit will contribute to unexposed person–years.

d 1.3: Measuring outcomes.

The main outcome of the study will be HIV incidence between inherited and uninherited widows.

Secondary outcomes will be different incident types of STIs: *N. gonorrhoeae*, *C. trachomatis*, *T. vaginalis*, *T. pallidum,* and *H. ducreyi*. A study among the Luos reported that WI practitioners maintained that the practice per- se is not a risk factor for HIV; rather, it is sexual activity of the widow, whether she is inherited or not. Contracting a STI, even when a client is HIV negative, will serve as a biological marker of risky sexual behavior and would validate reported behavior. Differences in sexual activity between inherited and uninherited widows could potentially affect the main outcome in that more risky sexual behavior by uninherited widows would dilute the effect of inheritance on HIV acquisition, if there is any, and will hence be monitored. Since clients with all STIs will be treated with an effective regimen,

those found on follow-up will be considered incident infections and will be used to detect an association between widow inheritance and STI acquisition. However, since syphilis takes up to 6 months before it clears from the system, a positive RPR would be considered incident case only from 6 month's follow-up. All symptomatic STIs will be treated syndromically following the standard of care recommended by the Ministry of Health (Appendix 2). Care will be modified, if needed, when lab results are out within two weeks.

d 1.4: Inclusion, exclusion and withdrawal criteria

To be eligible, a participant must be a widow (currently not remarried through religious, customary or civil ceremony), HIV negative, sexually active, aged 18-49 years, and a resident of one of the selected divisions in Bondo and Siaya districts in Nyanza Province for at least two months since the burial of the husband, with no plans to move out for the duration of follow-up (two years). In addition, she should consent to return for follow-up when she has an appointment and should consent to HIV counseling and testing at every scheduled visit. We have not put a restriction on the period of widowhood because the pressures that are normally brought to bear on the widows to push them into inheritance normally originate from many quarters, and span most part of widowhood [8]. For instance, they can come from her own grown up children who want to marry, build their own houses, plant their farms, etc., and fear misfortunes if their mothers do not discharge their sexual obligations. The widow's in-laws can also put pressure on her on behalf of her children, or so that she can get more and/or male children to continue the lineage of the deceased. Additionally, pressure can also be created from the widow's own parents and sisters, especially when death occurs in her maiden home and if she is an elder sister, she would be obligated to be sexually cleansed ahead of her other married sisters. There is also the requirement to observe sexual rites during farming seasons (cultivation, planting, weeding, and harvesting) and this is a lifetime commitment (except for older women who practice symbolic inheritance). Thus, it would not be practical to assign a precise time period within which children would mature and want to marry, build, etc., nor can we meaningfully talk about a time when a widow's sisters might get married or death occur in the family; we cannot even approximate a specific time period within which these pressures can coincide to create an intensely desired time period in widowhood when such pressures set on or one when they are still insignificant. Thus, ideally widows would qualify into the study any time after widowhood, but we have restricted their ages (18-49) on the assumption that by age 50, majority of the widows are getting out of active sexual life and the significance of inheritance that involves sex begins to diminish and slowly gets replaced by either symbolic inheritance or none at all because some of the sources of pressure begin to become irrelevant—children are grown, have established their homes, are married, etc. On the lower side, 18 years is the age of consent in Kenya, and widows below this age will not be considered for this reason.

Widows will be excluded from the study if, at enrolment, they are remarried (through civil, church, or traditional ceremony), HIV positive, if they are not sexually active, if they are not residents of the study divisions or plan to move out during the follow-up period, if they have not lived in the study division for at least two months prior to enrolment, or are unwilling to conform to the follow-up protocol.

Clients can withdraw from the study at will without losing any of the benefits associated with participation for the remaining part of the time when they would have been in the study, such as medical benefits, counseling services, or supply of condoms. The study also reserves the right to ask a client to withdraw from the study if her behavior is disruptive to other clients or is unreliable, but this will be done when the client has declined to change after repeated attempts by the PI and/or Project Coordinator to have her modify her behavior and after deliberations from the Executive Committee (the PI, the co-investigators, and the consultants).

d 1.5: Study sites

The proposed study will be conducted in the main health facilities in Maranda division of Bondo District and Boro division of Siaya District. The operations will be headquartered within the offices of IMPACT-Research and Development Consultancy in Kisumu, of which Mr. Obare, one of the co-investigators in the study, is a Deputy Director. The office is already equipped with 2 PCs and a laptop that the study will use on hire at a minimal fee. The study will beef up the equipment and renovate/partition as necessary. In addition, there will be two health facilities, both of which are district hospitals with enough space to lease to the project, also at a minimal fee. Locating the project at the health centers rather than at stand-alone sites would increase confidentiality of the participants since the public would not know their reasons for visiting the clinic.

Laboratory services will be offered at the UNIM project Lab detailed elsewhere. For specific and more specialized cases, the University of Nairobi Lab in the Department of Medical Microbiology will be used under Prof. Ndinya-Achola's supervision. Both Labs are equipped with state-of-the-art equipment and supplies.

d 1.6: Study area and population

Nyanza province accounts for 12% of the national population. The Luo ethnic community makes up 68% of the provincial population. In Kenya, Nyanza province has the highest HIV seroprevalence, with 29.8% of the cases in the country in 2001 [3,4]. Sentinel data by CDC/KEMRI show that in the province, the sites within the Luo-speaking districts recorded between 30.1% and 43.5% seroprevalence among women 18-49 years in 2000 [4]. A more recent preliminary report by CDC (January 2002) revealed that 50% of the widows going for VCT in their clinics across the province are HIV-positive [68]. For a study focusing on women, on widows, on their sexual behavior, on their HIV risk and vulnerability and on the impact of all this on the community, this scenario rationalizes the choice of Luo Nyanza as the study area. UNAIDS reports that 47% of the HIV cases in the world are women and out of these 81.9% live in Africa. Africa is the only region in the world where more women than men are infected. The peak HIV infection is between the ages of 25-29 years for women, and CDC reports that most widows seeking VCT are under the age of 30 years. Focusing a study of this nature on women, and more specifically on widows, takes research concern to a population that so desperately needs such attention.

d 1.7: Participant recruitment

Study subjects will be recruited in a variety of ways. General information about the study will be provided through Luo radio stations, posters, fliers, and announcements at the weekly meetings (*baraza*) convened by Chiefs and Assistant Chiefs. We will also compile a register of widows' groups (registered ones will be obtained from the Ministry of Culture and Social Services in the respective districts and the unregistered ones will be obtained from widows during focus group discussions). In addition, announcements made over the local radio channels, posters and fliers, and village barazas will reach also those who may not be members of organized groups. The key message in all the announcements will be that: "A research study of HIV is seeking participants who are widows between 18 and 49 years of age, living in (*name of division where the study will be carried out*), and who plan to remain in the said districts for a period of at least 2 years after joining the study. They must be willing to be counseled and tested for HIV. For more information, visit us at (*name of center*)". In addition, we shall constitute a Community Advisory Board (CAB) who will advise on strategies for community outreach, and also help with recruitment. Members to the CAB will comprise of one leader from a church supporting widow inheritance, one leader from a church that does not support WI, district chairpersons of widow's groups in Siaya and Bondo, district chairpersons of women's groups in Siaya and Bondo, district chairpersons of the Maendeleo Ya Wanawake Organization (a national umbrella of women's groups) in Siaya and Bondo, Chiefs from each of the 2 study divisions, the PI and the Project Coordinator (a total of 12 CAB members).

For every division, a widow who is in the study will be hired and trained as a peer recruiter-cum-tracer and an interviewer of behavioral questionnaire (if a client is traced but cannot come back to the clinic for the missed visit, the tracer would interview her if she consents). They will approach the officials of the local groups such as women's, widows' and church groups to hold information sessions and discussions with their members to inform them of the study, its goals, and the availability of HIV counseling and testing.

d 1.8.0: Visit schedule and data collection Forms

A series of forms have been developed to capture all relevant study data. These are:

0. *Visit Checklist Form:* Contains information on which forms are needed for which visits.
1. *Screening and Enrollment Form:* Contains information on study eligibility.
2. *Demographics Form:* Captures background information of women for baseline data
3. *HIV Consent Form:* Explains the process, risks, benefits, and confidentiality of HIV testing.
4. *Study Consent Form*: Explains the details of the entire study.
5. *HIV Test Results Form:* For recording HIV test results.
6. *Medical Exam Form:* For obtaining medical history and recording results of medical exams.
7. *Clinical Diagnosis Form:* To record diagnoses, prescription and management of clients.
8. *Laboratory Specimen Checklist:* To record Lab specimens and results.
9. *Locator Information Form:* To be used for tracing clients who fail to turn up for appointments (their ID #s will be deleted before being given to a tracer).
10. *Behavioral Questionnaire Form:* For interview on sociodemographic background and sexual behavior.
11. *Adverse Events Form:* To record any injury or untoward outcomes and classifying them in terms of their relatedness to participation in the study.
12. *Withdrawal Form:* For those who withdraw from the study, giving reasons for the withdrawal.
13. *Missed Visit Form:* For those who have not turned up for appointments. Visits will be considered missed if a client has not shown up by mid-point between the two consecutive visits.
14. *IRB Violation Form:* For recording violations such as breach of confidentiality, absence of clients' signatures on consent forms, linking a client's name and her ID # by persons other than the Receptionist Clerk, the PI and the Project Coordinator.

Drafts of the study forms are in Appendix 1, and the individual forms to be completed at each visit are indicated in Table 1.

P.I.

Table 1. Study forms to be completed at each visit.

0- Visit Checklist	x	x	x	x	x	x	x	x	x	x	x
1- Screening & Enrollment	x										
2 -Demographics	x										
3 - HIV Consent	x										
4 - Study Consent		x									
5- HIV Test Results	x	X if >2 weeks since last HiV test	x	x	x	x	x	x	x	x	x
6- Medical Exam		x	x	x	x	x	x	x	x	x	x
7- Clinical Diagnosis		x	x	x	x	x	x	x	x	x	x
8 -Lab Specimen & Results		x	x	x	x	x	x	x	x	x	x
9-Locator Information		x									
10- Behavioral Questionnaire		x									
11- Adverse Events		x	x	x	x	x	x	x	x	x	x
12- Withdrawal											
13- Missed Visit											
14- IRB Violation Form											

Note: HIV testing on follow-up visits is done only if there have been no previous positive tests. At unscheduled visits, Forms 0, 6, 7 and 11 are completed, and Form 8 if STD testing is indicated. Forms 12-14 are completed as needed and Forms 1-4 & 9 are filled only once. At subsequent HIV tests, clients will be reminded verbally of key issues of consent, such as risks and benefits of the test, as well as issues of confidentiality and rights to withdraw from the study or decline to participate in sections of the study. At these visits, they will also be reminded on how to interpret the results of the rapid test.

A study participant will be considered late for a visit if she does not present herself within two weeks after the scheduled visit date, except for enrolment where one week will be considered late and call for tracing. Because the clients will be retested for HIV if 14 days have elapsed since the screening test to minimize the possibility that she might have recently been infected, tracing will begin after 1 week post-screening to give clients time to join the study without going through another HIV testing.

d 1.8.1: Screening visit

At the clinic, the study will be explained to potential participants in more detail, and a nurse-counselor trained in protocol administration will offer HIV counseling and testing to those who give informed signed consent. Testing for HIV infection will be carried out using a double (parallel) rapid test protocol, as recommended by the Centers for Disease Control and Prevention (CDC) in Kenya. This comprises two different rapid tests (Determine and Unigold) being performed concurrently by a trained nurse-counselor during the visit. At the end of the pre-test counseling when clients provide informed and signed consent, charts will be used to take them through the process of the testing and how to interpret/read the results for themselves: positive, negative, discordant, and invalid results. Studies have found that clients in VTC centers prefer to receive results on the same day as the test [68], and preferably while they are watching, to remove the doubt that their specimens could have been mixed up if tests are carried out in the lab. Widows with concordant positive results will be informed of their HIV status and followed-up for continuing counseling, social support, and treatment of opportunistic infections at the health institutions where the study will be taking place. The cost of continuing care for positive participants will be borne by the clients; however, for those in the study who seroconvert, the project will pay for the cost-sharing charges at the hospitals whenever they are referred. In addition, we will form post-test support groups at each of the sites to run concurrently with the study—the groups will be used for sharing experiences and starting group-initiated and -run income generating activities. If the study is funded, we may apply elsewhere for a small supplemental fund to enable us to offer more services, such as provision of drugs for outpatient opportunistic infections. All clients regardless of their serostatus will be given a list of existing support groups in their respective zones where support can be obtained. According to a CDC report in February 2002, half of the widows going for VCT at their centers across Nyanza have tested positive for HIV. Antiretrovirals is not the standard of care in Kenya and will not be provided.

Also those with discordant results from the parallel tests will not join the study immediately; they will have venous blood specimen taken and sent to the University of Nairobi laboratory for further investigation by ELISA. Prof. Ndinya Achola, our consultant at the Department of Medical Microbiology at the University, will oversee the running of the tests. Since such individuals may be seroconverting at the time, they will only be enrolled in the study if the ELISA is negative and if, after another parallel rapid test performed after 1 month, the results are concordantly negative. Those with concordant negative will be invited to enroll in the study after a brief interview to ascertain their eligibility. At this point, the study protocol will be described to them briefly, and they will be given a copy of the consent form to take with them to read and if need be, consult over. Those who are unable to read will have the form read to them, with key points such us risks and benefits of joining the study, emphasized. They will be encouraged to think about it and to consult with whomever they wish. Those who agree will be given an appointment to return within seven days for enrollment.

d 1.8.2: Enrollment visit

At the enrollment visit, the study will again be explained to participants in detail and the counselor and each participant will go through the consent form carefully. Participants will be asked to participate, and if they consent, a medical history will be taken, they will be given a medical exam, specimens will be taken, and a questionnaire assessing sexual risk behavior will be administered. Data on sexual behavior

will include number and type of sex partners, use and frequency of sex for gifts or money, use of condoms, and use of lubricants or herbs by partner (dry sex). Socio-demographic data will include age, employment, education, religion, and inheritance status (details of the questionnaire in Appendix 1). Medical history will include, in addition to general medical conditions, a detailed history of genital or reproductive conditions, including a history of STD infections. After appropriate counseling and with consent given, approximately 10mls of blood (1 red top vacutainer) will be drawn to be used to test for syphilis antibody using RPR and *Treponema pallidum* hemagluttination (TPHA). In addition, 1 vaginal discharge swab will be taken for In-pouch culture for Trichomonas vaginalis (TV); and 1 cervical swab for Nesseria gonorrhea (GC) and Chlamydia trchomatis (CT) PCR. If present, genital ulcer swab will be taken for *Haemophilus ducreyi* (HD) PCR test. HIV rapid tests will be done on site; the PCR in Nairobi while the rest of the tests listed above will be performed in the laboratory at the UNIM clinic in Kisumu.

Procedure of taking specimens

Collection, transport, and processing:

Specimens to be collected: Venous blood and swabs (vaginal discharge swabs, cervical swabs, and if necessary, genital ulcer swabs).

1. Venous blood.

Site:

Label 1 red vacutainer tube with participant's ID# and Date.

Aseptically obtain 10 mls of blood into the red top vacutainer tube; put in a cool box and transport to the laboratory within 12 hours.

Laboratory:

Record the specimens by respondents ID #, number of tubes received and date.

Spin the tubes at 1200 rpm for 10 minutes in a centrifuge to separate the plasma and the serum.

i. Serum: Aliquot about 1.5 mls of serum into saerstaedt tubes (at least 3 tubes). Use one tube to do RPR (Qualitative and Quantitative) tests and TPHA.Freeze the other two in a -20^0C freezer

2. Swabs

a. Vaginal discharge swabs

Site:

Label 1 TV In-pouch bag and a microscope slide with client's ID # and Date.

With the participant lying in a dosal position and with clean gloves, use a sterile cotton swab to collect a sample of vaginal discharge from the posteris fornix.

Report the appearance of the discharge.

Make a smear to be stained by Gram's technique.

Use the same swab to inoculate the TV In-pouch bag and put the In-pouch bag in a cool box to be delivered to the laboratory within 12 hrs.

After the smear is dry, put in a slide box and transport to the laboratory in Kisumu.

Laboratory:

Log in the specimen log book the details by ID #, date and the specimen types received; open a worksheet for every client; incubate the TV culture In-pouch bag at 37^0C in the incubator for 5 days, examine for growth on the third and fifth day; and finally, stain the smear and write a report.

b. Cervical swabs.

Site: Label an AMPICLOR specimen transport tube with client's ID # and date.

With the participant lying in a dosal position and with clean gloves, use a sterile vaginal speculum to collect this specimen from the cervix, insert the speculum into the vagina to clearly expose the cervix. Pass a sterile cotton wool swab in to the endocervical canal and gently rotate 360^0 the swab to obtain the specimen. Put the swab in the dry AMPICLOR specimen transport tube, put in a cool box and transport to the laboratory within 12 hours.

Laboratory:
Log in the specimen receiving book by ID #, date, time of collection and the specimen type received; open a worksheet for every client, put the swab in the dry AMPICLOR specimen transport tube in a box marked GC and CT PCR SPECIMENS and store in a -70^0C freezer.

c. Genital ulcer swabs:

Site:
Label an AMPICLOR specimen transport tube with client's ID # and date. Cleanse around the ulcerated area using a swab moistened with sterile physiological saline. Using another sterile cotton tipped swab, gently rotate 360^0 it on the ulcer to obtain the specimen; insert into the AMPICLOR specimen transport tube, and put in a cool box to be delivered to the laboratory with in 12 hours.

Laboratory: Log in the specimen-receiving Book;
Put the tubes in a freezer box marked HD PCR SPECIMENS and freeze in -70^0C freezer.

Storage and transportation of specimens in the field

Field site for most of the field activities will be the existing divisional health facilities (Bondo and Siaya District Hospitals). These divisions have been selected because they have health facilities with adequate space to lease for the various activities of the proposed project. In addition, they have electricity which we will use for our refrigerators for storing specimens to await transportation to the Central Laboratory in Kisumu.

i. Field samples collection: All samples will be collected by trained staff against a detailed procedure in the *Field Sample Collection and Tracking Form* (To be provided by the Chief Lab Technologist) so as to minimize the possibility of sample loss. The collected samples will be put in the cool box for transport to a central collection point to await delivery to the main laboratory in Kisumu.

ii. Field-testing and storage of specimens: Due to the delicate nature of some indicator organisms, e.g. a urogenital parasite like *Trichomonas vaginalis*, some pre-laboratory field-testing and inoculation procedures will be done to ensure specimen integrity and organism viability. The clinician will be trained in the methods of collecting the specimens and in TV In-pouch inoculation, and in filling out the worksheet. The inoculated In-pouch bag will be kept in a refrigerator until delivery to the Main laboratory

iii. Specimen delivery to the main laboratory in Kisumu: To maximize the use of the collection van and avoid the possibility of some specimens being collected late or being left behind, a day's work will end at about 4.00 pm to enable the collection van to go around and pick all samples for delivery to Kisumu (around 80 kilometers to the farthest field site). A technician will receive the samples in Kisumu and perform the procedures outlined above in a Standard Operating Procedure that will be issued by the Chief Laboratory Technologist.

A senior Laboratory Technologist with several years experience from the CDC, Walter Reed, and currently, with an HIV/AIDS Project in Kisumu, will head the laboratory work in Kisumu. The laboratory at the Department of Medical Microbiology at the University of Nairobi laboratory, which currently supports a large number of clinical and epidemiological research projects and is very grounded in STD

diagnostics, will perform PCR and ELISA tests. Prof. Ndinya-Achola, himself an MD and a medical microbiologist, is a co-investigator in the study and will oversee the tests performed in Nairobi. Results will be returned via e-mail or fax to Kisumu and then to the respective centers. Study participants will be contacted and asked to return to the clinic if, based on the results, additional treatment is required before their next appointments. Those with complications will be referred to the main hospital/health center for specialized attention, at their cost, or benefit from the monthly visits by Dr. Elizabeth Bukusi, our gynecologist/obstetrician. All Laboratory tests will be performed against a rigorous quality control background using positive and negative control samples where necessary and a strict following of the kit manufacturer's instructions. The Chief Lab Tech has hands on experience in quality control methods & management from the Public Health Laboratory Services (Collingdale, London) and has participated in their quality control programs (National and External Quality Assurance Services) during his tenure at Wellcome Trust Research Laboratories/KEMRI-Kilifi.

d 1.8.2: Follow-up visits – 1, 3, 6, 9, 12, 15, 18, 21 and 24 months post-enrolment

At these follow-up visits, the following will take place: i) HIV counseling and testing will be given, ii) the diary that had been issued for recording sexual activity will be collected and new ones given out (for those who are illiterate, the envelopes will be collected and new envelops and beads given—see p...for explanation), iii) medical history will be taken, iv) medical exam will be performed, and v) the behavioral questionnaire will be administered. Those who test positive at 1 month will be considered to have been HIV infected at enrollment (the Unigold and Determine kits detect HIV antibodies within a month of infection). Follow-up will end at the Month 24 Visit, but if we obtain funding and start support groups, those with HIV who have joined the said groups will remain associated with the study, and receive continuing counseling and simple medication, until the end of the project (after 5 years).

d 1.8.3: Unscheduled interim visits

Interim visits to the clinics will be encouraged whenever the clients feel that they are in need of medical attention. At such visits, medical examinations and laboratory testing will be conducted as indicated, and appropriate treatment provided free of charge for common medical problems. Referrals will be made as necessary and the project will cover the cost of user-charges.

d 1.8.4: STD/HIV Counseling and follow-up

Those who test positive for any STD will be asked to return briefly to the clinic to receive their results, to be treated, and to receive additional counseling. Tracers will use locator information (with the ID #s removed) to trace clients if immediate treatment is necessary before their next appointment. The treatment will follow the standard guidelines set by the Ministry of Health (details in Appendix 2). Clients will also be given referral notes to take to their partners to seek treatment at their respective division hospitals. Arrangements with these facilities will be made in advance and the project will be responsible for the user-fee charges.

Trained and experienced *Dholuo*-speaking female nurse-counselors will provide HIV counseling and testing, with additional counseling provided by the clinical officer as required, also a *Dholuo*-speaker. Condoms will be provided free of charge to those who ask for them. Clients will be compensated for time away from work and for travel to the clinic for all regularly scheduled visits, at the rate of approximately $1.00 (80 Kenya shillings) per visit (this may be reviewed after Focus Group Discussions with potential participants at the start of the study where cost and ease of access to designated health centers will be discussed).

d 1.9: Adverse Events

These will include: i) Severe AE: Allergic reaction requiring hospitalization, arising from taking drugs dispensed by the project clinical officer (clients will be referred to the hospital where the project is stationed; the charges will be borne by the project). ii) Moderate AE: Fainting during specimen collection, more than normal bruising while taking specimens, domestic violence that causes bodily harm (bruises, cuts, swellings) because of joining the study, moderate allergic reaction to drugs that disrupts normal social activities but does not lead to hospitalization; iii) Mild AE: weakness when specimens are being taken, rejection by, or non-violent animosity from relatives or friends for joining the study; iv) Other AE: will be reported but will be considered unrelated to the study. All AEs related to the study will be reported every month to the relevant officials at NIH. If a specific type of AE is recurrent, we shall review our approach and modify accordingly. For instance, violence or rejection by family members may prompt us to ask the said family member to come over or the peer-recruiter can go to their homes, with consent from the client, and explain to them the study and address any issues they may have. Our plan of giving a copy of the study consent form to the clients to take home and consult over is one way of allaying such outcomes.

d 1.10: Retention of study enrollees

Loss to follow-up can reduce statistical power to detect a difference between the two study groups. If there is differential loss to follow-up between the two groups, this may also introduce bias. As such, we have put several measures in place to improve retention: i) we shall source our clients mainly from among widows who are residents of the study districts (these are widows who have continued to live in their rural homes for at least two months after the death of their husbands and are less likely to move out. ii) From the experience of the PI, Mr. Obare (a co-investigator) and Prof. Ndinya-Achola (a study consultant), Luo widows who have not returned to the cities upon burying their husbands and want to relocate will most likely move to other areas in the province, particularly in search of small business opportunities. They will be requested at enrollment that if they must move, they should inform the clinic or the peer recruiter about their new locator information. This way, if they do not return for visits, they can be traced. Widows enrolled in the study who have high school education will be hired and trained in tracing skills and conducting interviews. iii) If the tracers report that a client has left for another place and did not inform the project staff, efforts will be made to trace her. We shall get her contact address from her home without divulging any classified study information to her relatives and a tracer will try to locate her and, if necessary, interview her on sexual behavior. She will be requested to return for the missed visit and given bus fare if she needs it. iv) Giving clients modest refund for their bus fare and compensation for time at the clinic during scheduled visits will also serve as incentives for coming back for appointments. The amount ($1:00) is very modest and may not be construed as coercion given that to come to the clinic, clients will have forgone activities that provide them with daily food. v) It is anticipated that fear of testing positive may be a barrier to returning for follow-up, especially for those who may have engaged in risky sexual behavior since the previous HIV test. Starting a post-test support group, as well as prior experience of good counseling at previous visits, will be pull factors for return visits. And vi), helping the community by participating in the trial can also act as a drive for some clients to comply with the requirements of the protocol.

We shall prepare files for clients the day before their appointment. Files whose owners have not turned up for appointments will be placed in 'pending' trays until they come or for 14 days (7 days for enrollment visit) after which the owners will be traced. Files in the 'pending' trays will serve as physical prompts for late visits and tracing. The registering clerk will compile lists of those who are late and the PI or Project Coordinator will use their ID numbers to retrieve their locator information. A copy of the locator form, with the ID number deleted, will be given to the peer recruiter to trace her. However, clients who wish to withdraw from the study, for whatever reason, may do so.

d 1.11.1: Sample size determination

Data on HIV prevalence or incidence among widows in Nyanza province is sparse. Three research studies have been conducted among the Luo ethnic community on the relationship between HIV/AIDS and widow inheritance [8,10,11], but in none of them were participants screened for HIV to determine the prevalence in inherited versus uninherited widows. The only organization that has collected data on widowhood status during HIV testing is the Centers for Disease Control and Prevention in Kenya. Starting May 2001, CDC has put up four centers for Voluntary Counseling and Testing (VCT) across Nyanza Province [68]. By February 28, 2002, they had screened a total of 4,194 persons (66.7% of them female) of whom 21.9% were HIV seropositive. Widows between 18 and 49 years constituted 31.5% of the female clients, among whom 49.8% were seropositive. Forty five percent of the female clients were single women between 15 and 49 years, among whom 18.2% were seropositive for HIV. Given this background, and in the absence of data on seroprevalence or seroincidence of HIV in inherited or uninherited widows, this study has made two assumptions as a starting point in determining the sample size:

i. The seroprevalence among the widows aged 18-49 years (49.8%) is equivalent to the seroprevalence among inherited widows of the same age range. Ordinarily, it would be expected that the seroprevalence among inherited widows is higher (assuming inheritance is a risk factor), but because many widows going for VCT were those whose husbands had died of conditions suggestive of HIV/AIDS and/or those who were already sickly and suspected they were infected [personal communication with June Odoyo, MD, CDC Coordinator of VCT activities in Nyanza Province], this group is likely a self-selected high risk group. As such, we assume in this study that their prevalence is at least similar to inherited group.

ii. The seroprevalence among single women 15-49 years (18.2%) is equivalent to that of uninherited widows. The assumption is made on the basis that both uninherited widows and single women are not in steady unions, hence their sexual behavior and subsequent risk is likely to be similar.

Given the two assumptions, the relative risk (RR) associated with being inherited would be 2.7. However, so as to be conservative, we are assuming a relative risk of between 1.3 and 1.5 among inherited widows compared to uninherited widows. We have used Epi Info statistical software to determine the sample size from which we would detect a 1.3 to 1.5-fold difference between inherited and uninherited widows in HIV prevalence, at a confidence interval of 95% and a power of 90%. First, we assume 50% prevalence among inherited widows (see assumption 1 above) and 18% prevalence among uninherited widows (see assumption 2 above) to arrive at a sample size of 100 in the two groups. Secondly, we assume a prevalence of 35% among inherited widows and, again, 18% among uninherited widows and arrive at a sample size of 302 in both groups. Thirty-five percent is the average seroprevalence of women at sentinel sites across Nyanza and would serve as an average for women with regular sexual partners as inherited widows would be. Finally, to be even more conservative, we assumed 40% seroprevalence among exposed (inherited) widows and 30% among unexposed (uninherited) widows, giving a sample size of 992. We have used 40% and 30% prevalence among inherited and uninherited widows, respectively, because we recognize that 50% reported by CDC among widows might have been inflated as many of the clients seeking testing were already sickly. There is also the argument by the practitioners of widow inheritance that the practice checks the spread of HIV by potentially restricting the number of sexual partners. Forty-one percent is the highest prevalence reported among married women in sentinel sites across Nyanza Province, whom inherited widows would replicate. The choice of 30% is based on the assumption that, again as the practitioners of inheritance argued, uninherited widows, not being in a regular relationship from where they can get economic and other support, are more likely to engage in casual sex and to have multiple sexual partners. As such, their seroprevalence would be higher than the 18% reported by CDC for single women. Using these prevalence estimates, we expect to recruit into the study 992 participants.

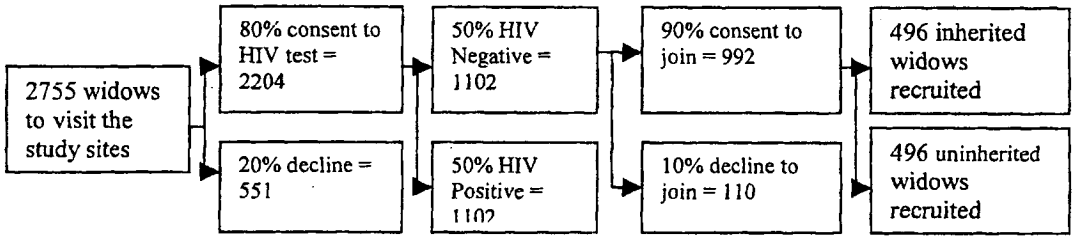
Table 2: Sample size determination (at 95% CI and 90% Power)

Prevalence in inherited (%)	Prevalence in uninherited (%)	Sample size of inherited	Sample size: uninherited	Sample Size: Total
50	18	50	50	100
35	18	151	151	302
40	**30**	**496**	**496**	**992**

The two divisions selected for the study together have a female population of 111,881 [2]. The National Population Census of 1999 has not reported the number of widows, but a report from the Ministry of Culture and Social Services show that 661 widows' groups were registered in the two study divisions in the year 2000, with membership ranging between 15 and 40 [69]. The report also estimated that for every five groups registered, there are two unregistered groups, and also that there are many widows who are not in either registered or unregistered groups. With this estimate, we can assume a source of not less than 16,000 widows from the registered groups, some 7,000 or more from unregistered groups, and others who are not members of any organized grouping. Thus, we expect to have well over 20,000 widows within the divisions, of whom we expect the majority to be between 18-49 years of age (ALL widows presenting for HIV testing at the CDC clinics between May 2001 and February 2002 were under 45 years of age [68]). Basing our estimation on data from CDC, which reported that 50% of the widows going for CVT were positive (we have used 50% in order to be conservative even though our sample size estimation is based on a 40% seroprevalence), we anticipate that half of the potential clients approached will be ineligible. Also, others will decline to join the study for various reasons, especially for fear of knowing their serostatus. Since there is no study that has specifically screened widows for HIV in Nyanza, anecdotal information from a Community-Based Organization for widows with which the PI is affiliated (Barchando Widows and Orphans Group in Maranda Division, Bondo District), 87% of the widows joining the organization agreed to be tested for HIV. And in an ethnographic study on widow inheritance and HIV by the PI in 1999-2000, most of the women who attended Focus Group Discussions, many of them widows, requested to be tested. Also, the most common recommendation provided by the participants to reduce the potential risk associated with widow inheritance is that both the widow and the inheritor should be tested for HIV prior to entering into any sexual contract. CDC and the Ministry of Health have also put in place intensive campaigns for people to know their serostatus through Voluntary Counselling and Testing in various health facilities and this has markedly improved the number of people seeking these services (68,70]. Thus, it is highly feasible that widows will agree to be tested, and we estimate that at least 80% of those who come to the study would consent to being screened and 90% or more of those screened would eventually join the study.

Given these estimates and assumptions, we expect 2755 widows to pass through our hands, of which 2204 (80%) will be recruited for HIV counselling and testing (20% may decline to be tested or will be ineligible for various reasons). Half of them (50%) could be HIV-positive and ineligible and of the 1102 remaining, 10% may decline to join the study. Nine hundred and ninety two widows will participate in the study (The process is graphically shown in Fig. 1 below). Everyone who meets the eligibility criteria will be recruited in the study. Participation in any part of this project is voluntary and participants can withdraw from the study at any time, or they may refuse without penalty to provide any specimen or to answer any item or series of items that they are asked during interviews.

Figure 1: Subject Selection Process



d 1.11.2: Analyses:

Screening: Frequency of reasons for exclusion from study (temporary and permanent) will be reported. This will provide useful data to assess the seroprevalence of HIV among those who are inherited and uninherited at the start of the study. We will calculate the relative prevalence and 95% Confidence Interval.

Baseline: Baseline characteristics of clients (age, religion, education, employment, income, number and type of sexual partners, results of medical examination, results of reported STDs, frequency of exchanging of sex for money or gifts, condom use, etc) will be compared between those who are inherited at the start of the study and those who are not. Unpaired t-test and chi-square test will be used to analyze differences among exposure groups of continuous and categorical variables, respectively.

Primary Outcome Measure: The primary outcome measure will be the HIV seroconversion rate during the two years of follow-up.

Analysis of the primary outcome measure:

1. We shall use Epi-Info software to enter data and to perform crude and adjusted Mantel-Haenszel tests (using 2 X 2 tables) to obtain the relative risk of acquiring HIV given that a widow is:

   a) Inherited, relative to those who are not inherited

   b) Inherited for purposes of companionship and support, relative to those who are:

      i. inherited for purposes of sexual cleansing.

      ii. not inherited

   c) Inherited by a brother-in-law, relative to those who are:

      i. inherited by a non-relative (professional inheritor)

      ii. not inherited

   d) Inherited by a brother-in-law for purposes of companionship, relative to those who are:

      i. inherited by a professional for purposes of observing traditions of sexual cleansing

      ii. not inherited.

The analyses will also be done by stratifying the widows by condom use, incidence of the various STIs being tested, number of sexual partners, and the sociodemographic variables being collected.

2. We shall determine factors associated with inheritance overall, and those associated with the different types and purpose of the practice, by performing logistic regression analysis to identify which characteristics (e.g., religious doctrines, background characteristics [sociodemographic factors] and societal responsibilities and obligations) are independently related to inheritance.

In a sub-analysis, widows who seroconvert as of 1 month after enrollment will be excluded since they likely developed HIV infection prior to enrollment (the test kits we will use—Determine and Unigold—are capable of detecting HIV antibody in the blood within a month of infection).

Analyses adjusted for baseline covariates: Cox Proportional Hazards analysis will be used to estimate the magnitude of the effect of inheritance on HIV incidence, after adjusting for baseline measures of demographics, medical examination, STD laboratory tests and reported sexual risk behavior. These analyses will also identify which baseline covariates are significant predictors of HIV seroconversion within 2-years. The analysis will be repeated for the different types and purposes of inheritance. Person-years of exposure will be used instead of individual count of widows. Determination of person years is discussed elsewhere in the proposal.

Analyses adjusted for behavioral differences after enrollment: Inheritance or lack thereof might potentially alter the subject's sexual behavior, which could affect the subject's risk for HIV infection. To take this into account, statistical modeling will be repeated by adding variables measuring the participant's sexual behavior during follow-up (number and type of sexual partners, condom use, history of offering sex for money, etc) and observe the effects of these potential mediators on the association between inheritance and HIV seroconversion. Cox proportional hazards regression analysis will also be done, with the dependent variables being HIV conversion at intervals of follow-up and the independent variables being inheritance status and baseline co-covariates used in the logistic regression analysis described above.

Analyses of secondary outcomes: The same method described for analyzing HIV seroincidence will be used to analyze STD seroincidence.

Other analyses: We shall use information at baseline to compare the characteristics of those who are lost to follow-up or those who withdraw with those who remain in the study. Because progression from HIV to AIDS-related condition or death is expected to be slow since we shall be starting out with those who are HIV-negative, it is unlikely that drop-outs will be due to death. However, it is possible that the risk of seroconversion is different for drop-outs compared with those who remain in the study. We will estimate the effort of differential dropout on our study results.Self-reported sexual behavior versus STD lab test: We shall compare lab results with reported sexual behavior. The results would be useful in assessing the validity of self-reported information and would help us to estimate the effects of information biases on our study results.

d. 1.12: Possible limitations and alternative approaches

There are obvious potential problems that must be ingeniously circumvented to ensure the success of this proposed study. The most prominent one is that of getting enough population of HIV negative widows in the study area to build enough sample size. This is so given, as already mentioned, that majority of deaths now are HIV-related and also that spousal loss through death is so traumatizing that some widow may be averse to the use of their widowhood status to qualify them into a study. Although we have put into place several approaches of enrolling and retaining participants in the study (details in "Participant recruitment" section and "Retention of study enrollees"), we may still not meet our required sample-size. We shall monitor accrual rate and if by mid-term we are 25% or more below target, we shall expand to adjacent divisions in the same districts: Madiany in Bondo district and Yala in Siaya district. Both divisions have the second largest health facilities after the two we shall be using, hence there will be space available to house the study.

There is also a likelihood that by offering intensive risk-reduction plans through counseling, HIV testing, treatment of STIs, and distribution of condoms, we may compromise the generalizability of the results. In other words, if we find no association between widow inheritance and HIV acquisition, it may be because all widows have been convinced to reduce their risk, e.g. by using condoms, whether or not they are inherited. However, it would be ethically wrong to withhold information or treatment from the clients, even if this would be the model of the normal situation, so that we can get an answer to our study question. If sample size allows, we will stratify widows by risk reduction plans in the analyses, e.g., use

of condoms, treatment of STIs, etc to assess the effect of these variables on HIV incidence. But we may never know if our results are affected by the counseling that we shall provide. Another potential limitation that is worth discussing: what are the implications of basing a study on volunteers? Need to say that, even if the women who choose to participate in this study have an incidence of HIV acquisition that is atypical of all widows, there is no reason to believe that there is incompatibility between those who are and are not inherited (beyond those characteristics that will be measured and adjusted for).

d. 1.13: Use of findings

After data analysis, we will circulate a summarized version of the findings and recommendations to all stake holders in HIV/AIDS intervention in Luo Nyanza and beyond – e.g. various community based groups, churches, local opinion leaders, NGOs, Government departments; schools, colleges, universities and public libraries, etc. One or two local dailies will also carry a review and /or press conference on the same. Eight two day workshop/seminars will also be held in each of the 8 district headquarters of Luo Nyanza, bringing together representatives of the mentioned stake holders in each district to get research feedback and together chart out way forward. The electronic media will also carry a press conference on the same research. Such dissemination of research findings is the surest way of accessing policy makers, planners, development practitioners and other relevant persons to the only available scientific information on this research question and is considered a terminal imperative to a study exercise of this magnitude and import.

d. 1.14: Time frame

This study is proposed to span five years, starting December 2002. The initial six months will be used to set up the preliminaries like setting up office space within Impact-RDC offices and getting it ready for use as specified in the above section, getting the UNIM/University of Nairobi Labs set up for this component of the study, assembling and training the study team on all aspects of the protocol, pre testing and finalizing all forms and questionnaires and developing the final operations manual. Reconnaissance study area visits and mock trials in the site centers will be carried out for purposes of familiarization by the study team. The team will be trained on the details of the operations, handling of study forms and questionnaires, etc. The Principal Investigator will supervise these activities continuously initially on a full time basis after securing three months' leave from the University of Nairobi's UNIM Project which she is coordinating. She will work half time for the subsequent period until the end of the study.

Recruitment is anticipated to take 24 months, making is possible to process an average of 3 clients per day per site and to enroll 1-2 clients daily into the study. This is based on seeing a total of 2755 widows and screening 2204 (80%) for HIV. Out of these, it is expected that 50% will be seropositive for HIV and 10% would decline to join the study after screening (details of these estimations are discussed above under "Sample Size Determination". Handling 3 new clients per day is considered reasonable based on the fact that public transport to the study site may be cumbersome to some clients, and also that domestic commitments would keep some away from coming on particular days. However, the project staff will be busy with all the return appointments besides the new visits. Recruitment will end on the 30th month of the research period. Follow up time-tables for subjects will depend on individual recruitment date. Because of this, we will count another 24 months follow up period after the 30 months that end recruitment. This means that follow up will end with the 54th month leaving the final 6 months for data analysis, report writing, presentations to the local and international policy, planning, programme and academic consumers as well as the scientific communities both locally and internationally. There will be a mid-term interim analysis to evaluate the success of the approach and to see if there is need for review.

e. 1.0: Human Subjects

e. 1.1: Protection of Human Subjects

To minimize risk of disclosure to others and discrimination or stigmatization, all measures will be taken to ensure confidentiality. Each participant will be assigned a confidential code number to be used by staff when collecting and reporting information. Only the PI, the Project Coordinator (Mr. Obare) and the receptionist-clerk will have access to files matching personal identifiers to confidential code numbers for the purposes of contacting study participants and follow-up data collection. Nothing in these files will indicate the nature of the client (e.g., there will be no mention of inheritance status, STD history, or sexual behavior), nor will the lists contain results of any biologic testing. For each center, three copies of these files will exist: a hardcopy, a copy in a computer hard disk (laptop) and a backup on a floppy. The floppy will be backed up on the project PC at the project headquarter in Kisumu will be accessed by password known only to the PI and the Project Coordinator. The hardcopy will be stored in a locked cabinet at the project site and will be accessible only to the receptionist clerk, the Project Coordinator, and the PI. Locator information without links to confidential code numbers will be shared with peer-recruiters for tracing purposes.

Research staff will use coded forms and confidential code numbers for study participants when collecting and processing test data. Laboratory samples and results will be identified only by confidential code numbers. At no time will the project release medical or laboratory information that could in any way be linked to a particular study participant. Publications and scientific presentations of the findings from the study will be presented in aggregates and without the identities of individual participants.

For emotional stress related to positive results of serological or other tests, the project will undertake to arrange for post-test counseling and referral to the respective health facility where the study is located for continuing counseling and medical attention. We shall also refer them to existing social support groups of PLWHA. CDC has instituted such groups in Maranda division. In Boro division, we shall use the referral approach in place at the VCT clinics.

All participants will be encouraged to come to the clinic at any time they are ill for examination and treatment. In cases where the clinic is not equipped to attend to the participant, he will be referred to the adjacent hospital for further attention. For possible side effects caused by medication taken at the clinic, we have included questions on allergy to drugs during interview on medical history and will be able to pick up most of these cases. In addition, the clinical officers who will be making diagnoses and dispensing drugs will have extensive experience with the standard syndromic management of STIs (algorithm in appendix 2). Any complications that cannot be managed at the clinic will be referred to the main health facility where the project is located. All drug-induced allergies will be recorded as AE related to the study and reported to the co-investigators and consultants (the Executive Committee), as well as to the NIH.

In case there is violence associated with participation in the study, we shall seek audience with the person(s) and explain the study to them, and address any issues they may be having. Also, giving them the consent forms to take home and consult over will reduce the likelihood of having such incidents as it is expected that the client will have shared her intention to join the study with family members prior to enrollment.

The elaborate consent form addresses the issue of erroneously feeling safe because one has tested negative or is not inherited. There will also be extensive counseling on risk reduction behavior.

e. 1.2: Inclusion of Women:

Since the proposed study is on widow inheritance, all the participants will be women. The Characteristics of the study population is as follows: we propose to recruit widows between 18 and 49 years old, not remarried through religious, customary or civil ceremony, HIV negative, sexually active, and a resident of one of the selected divisions in Bondo and Siaya districts in Nyanza Province for at least two months. They should have no plans to move out for the 2-year duration of follow-up. We shall exclude widows who, at enrollment, are remarried, HIV positive, not sexually active, not residents of the study divisions or plan to move out during the follow-up period. They will also be excluded if they have not lived in the study division for at least two months prior to enrolment, or are unwilling to conform to the follow-up protocol.

We expect 2755 widows to visit our centres, of which 2204 (80%) will be counselled and tested for HIV (20% may decline to be tested or will be ineligible for various reasons). Half of them could be HIV-positive and ineligible (CDC found 50% of the widows tested at their VCT centres to be positive for HIV [68]) and of the 1102 remaining, 10% may decline to join the study. Nine hundred and ninety two widows will participate in the study. Everyone who meets the eligibility criteria, regardless of ethnicity, will be recruited in the study (98% of the people living in the selected divisions are of the Luo ethnic community [2]). Above all, participation in any part of this project is voluntary and participants can withdraw from the study at any time without penalty.

e. 1.3: Recruitment and consent procedures

Widows will be contacted initially through organized groups such as widow's groups, women groups, and churches. We shall also use local *Dholuo* radio stations to spread word about the study. Other channels of reaching out will be through posters, fliers, and brochures given out/put up at health centers, bus stops, market places, and sources for domestic water where almost all rural women visit daily. Announcement will also be made at the weekly meetings (*baraza*) convened by Chiefs and Assistant Chiefs, as well as during health talks in health centers in the study area. For each division, two widows who are in the study will be hired and trained as peer recruiters to disseminate information in the community about the study, its goals, and the availability of HIV counseling and testing. We will also use members of the Community Advisory Board (CAB) to advise on strategies for community outreach, and also help with recruitment. Members will consist of leaders of churches (2 members), widows' groups (2 members), women's groups (2 members), Maendeleo Ya Wanawake, a national women's organization (2 members), chiefs from the 2 study divisions (2 members), the PI and the Project Coordinator

Those who come to the clinics will be provided with intensive private counselling on sexual risk reduction, including training in the correct use of condoms. They will be informed of the study, its goals, eligibility for enrolment, the procedures they will be asked to go through, and the potential risks of participating. Those who are willing to participate in the study will be requested to give voluntary informed consent for a fingerprick blood draw for the initial HIV test. We shall use two parallel tests recommended by the Center for Disease Control and Prevention and approved by the Ministry of Health. Those who are positive will be informed of the results, provided with post-test counselling. They will be encouraged to form post-test social support groups, which will be overseen by the project staff. The widows themselves will however take lead in running it. In addition, we will link them up with existing groups where they can obtain additional psychosocial support, and also with the support programs of the facilities within which we shall be working, to provide treatment for opportunistic infections. If the project is funded, we may look for small supplemental funds to start a post-test support group where we can also provide simple treatment for the clients with HIV at screening. However, those who seroconvert during the course of the study will continue to get free medication for the entire duration of study and not just for the two years of participation.

Whoever is HIV negative on the basis of two parallel rapid tests and who also meet other eligibility criteria (HIV negative, sexually active, aged 18-49 years, and a resident of any of the 2 study divisions, etc) will be eligible for enrolment in the study. The study will then be explained to her in more detail, including the potential risks and benefits of participating, and assurance of confidentiality. All the nurse-counsellors will be *Dholuo*-speaking females who will be able to give clear explanation in the local language. Once all questions have been answered and the counsellor is confident that the subject understands all the procedures, she will be asked for her signed consent to participate in the study. At each centre, all consent forms will be locked in a cabinet, accessible only to the receptionist-clerk at each center, the PI and the Project Coordinator.

During subsequent visits (1, 3, 6, 9, 12, 15, 18, 21, and 24 months after enrolment), participants will receive additional counselling about safe sexual behaviour and other HIV prevention strategies, and those who want condoms will be given. They will also be asked to give separate verbal informed consent for every HIV and STD test.

e. 1.4: Specimens to be collected

We shall collect approximately 10mls of blood to be used for syphilis antibody test (RPR and *Treponema pallidum* hemagluttination--TPHA) and HSV-2 ELISA test. We shall take a vaginal discharge swab to be used for Tv examination by in-pouch culture, as well as a cervical swab for GC PCR. If genital ulcer is present, a swab will be taken for *Haemophilus Ducreyi* (HD) PCR.

e. 1.5: Potential risks

Some of the interview questions may result in embarrassment or emotional distress. Also, there is possible risk of widows who test positive becoming stigmatised by family, friends, or neighbours; some may face violence by family for participating in the study. There are also risks involved in HIV testing if results are not kept confidential, and there are risks of psychological stress and depression to those who test positive. There could be risks involved in taking the specimens, including fainting or excess bruising. There is also some risk of side effects to drugs administered to cure STDs. In addition, widows who test negative may engage in more risky sexual behaviour, and so would be uninherited widows who may wrongly assume that only inheritance is associated with risk for HIV

e. 1.6: Inclusion of Minorities: Not applicable in the study population

e.1.7: Inclusion of Children: Not applicable because the study is on widows

e. 1.8: Data and Safety Monitoring Plan: Not applicable because the study is not a clinical trial

f: **Vertebrate Animals:** Not applicable for the proposed study

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April 12, 2002

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040 MSc 7710
Bethesda MD 208892 - 7710

Dear Sirs

RE:

I write in support of I who has submitted a proposal and is requesting for a grant from NIH.

The subject which I intends to study "The Association Between Widow Inheritance and HIV Incidence in Kenya" is one that has attracted attention of Scientists, Political and religious leaders as well as health workers in many African settings where widow inheritance is practised. While there may be reasons to believe that widow inheritance increases the risk of HIV infection, the evidence at the moment is annecdotal, and there is a compelling need to have proper data.

has the right qualifications and ability to conduct such a study. At the moment s employed by the University of Nairobi working in a research project located in the area where her proposed study is intended to take place. Dr.) will continue with her employment status in the University of Nairobi and will receive her salary.

Yours Sincerely

PROFESSOR J.O. NDINYA-ACHOLA
AG. DEAN, FACULTY OF MEDICINE

UNIVERSITY OF WASHINGTON
INTERNATIONAL AIDS RESEARCH AND TRAINING PROGRAM

11 April 2002

UNIM Project
PO Box 1764
Kisumu, Kenya

Dear

I am writing in enthusiastic support of your NIH grant application, "The Association Between Widow Inheritance and HIV Incidence in Kenya."

As you know, the University of Washington has been involved with collaborative AIDS research in Kenya for over 15 years. In 1988, we established the International AIDS Research and Training Program with two grants from the Fogarty International Center and we have provided training to ~50 Kenyan scientists. When you applied for IARTP support for your graduate work at the University of Washington (you were a Fulbright Fellow at the time), we were particularly enthusiastic about your candidacy because of your combined interest in Medical Geography and Epidemiology. Particularly in the international arena, there is a paucity of investigators with combined social science and public health expertise and there is certainly a great need for behavioral/epidemiologic research in the field of HIV-1 prevention in subSaharan Africa.

The project on widow inheritance you are proposing is unique and of potentially great importance not only in Kenya but in a number of other African countries in which widow inheritance is practiced. The project is challenging, but this was also the case for your circumcision study, and I was very impressed by your ability to plan and conduct extremely high quality research under difficult field conditions.

The goal of the IARTP is to foster international collaborative AIDS research, so I am very pleased that you are expanding the Kenya/University of Washington collaboration with your proposed widow inheritance and HIV-1 project. I offer you the enthusiastic support of the IARTP. You have a track record of success, and I am sure you will conduct this project with your characteristic excellence. I believe you to be a perfect candidate for these new Global Health Research Initiative grants.

Sincerely,

Joan Kreiss

Joan Kreiss, MD, MSPH
Professor
Departments of Medicine and Epidemiology
Director, International AIDS Research and Training Program

JK/ap

325 Ninth Avenue Box 359909 Seattle, Washington 98104-2499 USA 206-731-2822 FAX: 206-731-2427 Email: iartp@u.washington.edu

UNIVERSITY OF WASHINGTON

DEPARTMENT OF EPIDEMIOLOGY
School of Public Health and Community Medicine

April 12, 2002

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710

RE: RFA-TW-02-002: K[illegible] Ph.D.,
"Widow inheritance and HIV infection"

I'm writing in support of the grant application of [illegible], and also to indicate my interest in serving as her mentor on this project. I have known Dr. Agot for several years, first serving as her instructor in two courses in Epidemiology, and then as the Chair of her masters thesis committee in the Department of Epidemiology.

[illegible] became interested in epidemiology while she was pursuing her PhD degree in the Department of Geography here at the University of Washington. She conducted what was possibly the most ambitious Masters thesis research in the history of our Department, namely, a cross-sectional survey of circumcision in relation to HIV prevalence in rural Kenya. This was a large, complex and logistically difficult project to take on. Nonetheless, Dr [illegible] applied for and received funding to conduct it, and then personally led a research team in carrying it out. In the end, she and her staff recruited over 1,000 rural Kenyan men into the study, and was able to address the issue of circumcision as a risk factor for HIV infection in as good or better a manner as had previously been done. Specifically, by comparing the prevalence of HIV infection among circumcised and non-circumcised men who otherwise were from a relatively homogeneous population, she was able to tease out the effect of circumcision from other risk factors with which it is commonly correlated elsewhere. Her observation of a 50% higher prevalence of HIV in circumcised men is an important result, one which will be published in a prominent medical journal in the near future.

If credit for the conduct of this impressive study were to be apportioned, some 95% would have to go to [illegible] herself. It was she who identified the research question, the research setting, and the resources with which the study could be done. She did make excellent use of myself and other faculty in Seattle, primarily to sharpen the design and analyses. I found Dr.

F263 Health Sciences Center Box 357236 Seattle, Washington 98195-7236 (206) 543-1065 FAX: (206) 543-8525

pleasure to work with. She proved eager to apply epidemiologic methods and principles to her study, and eager to receive input from her mentors. Dr. s enthusiasm for her work was transmitted to all of us with whom she dealt.

With regard to her current proposal, I have been impressed with its ability to unite the strengths of the social sciences and of epidemiology, creating a whole that is well more than the sum of the parts. Studies such as Dr. Agot's on widow inheritance will be essential if we are to understand the role of cultural practices and attitudes in [redacted] of HIV infection. Though the proposed investigation is an ambitious one, I believe that the research team that Dr as assembled, both in Africa and the U.S., is up to the challenge.

Though most of my research has focused on cancer epidemiology and clinical epidemiology, I have previously worked with several African scientists on HIV-related research, notably Dr. Dr. Gerard Gresenguet of the CAR, and Dr. Elizabeth Bukusi of Kenya. I believe I have a contribution to make to the methodologic aspects of these investigations, and very much look forward to continuing my involvement with them.

Sincerely,

Noel S. Weiss, MD, DrPH
Professor

[redacted]

[redacted]

[redacted]

[redacted]

P.I. [redacted]

April 15, 2002

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710

RE: RFA-TW-02-002: [redacted], Ph.D.,
"Widow inheritance and HIV infection"

I am writing to enthusiastically support Dr. [redacted] study proposal of the relationship between widow inheritance and HIV transmission and to express my interest in working with her as a mentor on this project. I have had the privilege of mentoring Dr. Agot through her graduate studies at the University of Washington and served as the epidemiologist member of her doctoral dissertation committee.

Dr. [redacted] as demonstrated high potential to become an outstanding scientific leader. Her training and experience at the interface between the social and public health sciences and her intimate understanding of the complex relationships between health and culture on the African continent have positioned her to make a unique and valuable scientific contribution. In her grant application Dr. [redacted] proposes to apply rigorous epidemiologic methods to an important public health question that she is uniquely situated to address.

I cannot speak highly enough of the academic and personal strengths that Dr. [redacted] brings to this project. As evidenced by her impressive curriculum vitae, over the past decade, Dr. Agot has received numerous international fellowships and awards to conduct research in rural Kenya. During her tenure as a graduate student at the University of Washington, Dr. [redacted] successfully designed and conducted an ambitious study that addressed two very different questions and served as her master's thesis in epidemiology and her doctoral dissertation in geography. These works contributed valuable information and perspectives to a base of scientific evidence on cultural practices and the occurrence of HIV. To conduct her master's thesis, Dr. [redacted] applied similar quantitative research methods that she will use in the proposed observational study. In her doctoral dissertation, Dr. Agot laid the groundwork for addressing the topic of her proposed study.

Over the past five years, I have worked closely with Dr. [redacted] to mentor her during the development of her thesis and dissertation proposals. She was a brilliant student. In each setting where I have observed her, Dr. [redacted] rose to the

top to stand out as exceptionally thoughtful, creative, energetic, and capable. An asset that will ensure the success of the proposed project is Dr. [redacted]s ability to convene and lead a strong multidisciplinary research team that is needed to achieve the proposed research goals. Her training and research experience in geography, general social science, and public health will be key as she addresses the complex methodological and logistical issues this study will raise. Being a native of the Luo District of Kenya, increases Dr. [redacted]credibility in navigating and describing the cultural context in which the study will be conducted.

Of the students I have encountered in my professional career, I cannot think of anyone whom I would judge to be more capable than Dr. [redacted]. She has already launched a remarkable career that I know will continue to flourish and bear fruit. Furthermore, she has committed her talents to addressing issues that are of pressing importance to human health.

As a research methodologist who also works at the interface of health and social sciences, I look forward to this opportunity to continue to mentor Dr. [redacted]. On the project she proposes, I will help her to address issues in the areas of design, analysis, interpretation, and writing. My research career began in East Africa, and I look forward to the opportunity to contribute to the well-being of its population.

Sincerely yours,

Ann Vander Stoep, PhD
Assistant Professor
Department of Psychiatry and Behavioral Sciences
Adjunct Assistant Professor
Department of Epidemiology

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Widow Inheritance and HIV Infection in Kenya

[redacted]

Total Planned Enrollment: 992

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
[redacted] **Ethnic Category**	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or [redacted]	0	0	0
Not Hispanic or Latino	992	0	992
Ethnic Category Total of All Subjects*	992	0	992
[redacted] **Racial Categories**			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	992	0	992
White	0	0	0
Racial Categories: Total of All Subjects *	992	0	992

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Principal Investigator/Program Director (Last, first, middle):

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☒ NEW application. *(This application is being submitted to the PHS for the first time.)*

☐ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No. _____ ☐ SBIR Fast Track

☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. _____ ☐ STTR Fast Track

☐ REVISION of application number: _____

(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

☐ COMPETING CONTINUATION of grant number: _____

(This application is to extend a funded grant beyond its current project period.)

INVENTIONS AND PATENTS *(Competing continuation appl. and Phase II only)*

☐ No ☐ Previously reported

☐ Yes. If "Yes," ☐ Not previously reported

☐ SUPPLEMENT to grant number: _____

(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of principal investigator/program director.

Name of former principal investigator/program director: _____

☒ FOREIGN application or significant foreign component.

1. PROGRAM INCOME ***(See instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)
N/A	0	0
N/A	0	0
N/A	0	0

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/ certifications are provided in Section III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects; •Research Using Human Embryonic Stem Cells• •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals• •Debarment and Suspension; •Drug- Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☐ DHHS Agreement dated: _____ ☐ No Facilities And Administrative Costs Requested.

☐ DHHS Agreement being negotiated with _____ Regional Office.

☒ No DHHS Agreement, but rate established with University of Nairobi Date 04/11/02

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $	50,000	x Rate applied	8.00	% = F&A costs	$	4,000
b. 02 year	Amount of base $	50,000	x Rate applied	8.00	% = F&A costs	$	4,000
c. 03 year	Amount of base $	50,000	x Rate applied	8.00	% = F&A costs	$	4,000
d. 04 year	Amount of base $	50,000	x Rate applied	8.00	% = F&A costs	$	4,000
e. 05 year	Amount of base $	50,000	x Rate applied	8.00	% = F&A costs	$	4,000
					TOTAL F&A Costs $		20,000

*Check appropriate box(es):

☒ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

4. SMOKE-FREE WORKPLACE ☒ Yes ☐ No *(The response to this question has no impact on the review or funding of this application.)*